

OPTIONS FOR A REVISED FRAMEWORK FOR SETTING AND REVIEWING BENEFITS FOR THE PROSTHESES LIST

Report of the Menzies Centre for Health Policy, University of Sydney, on proceedings of the Prostheses List Revised Benefit Setting & Review Framework Industry Working Group (BSRIWG) and options for reform

Version 7.0

December 2020

TABLE OF CONTENTS

Executive Summary	3
Introduction	5
Purpose of the Prostheses List.....	5
Criteria for inclusion on the Prostheses List.....	5
Prostheses List grouping structure.....	6
Setting Prostheses List benefits.....	6
Reviewing Prostheses List benefits	7
Infrastructure to support the Prostheses List.....	7
Current Prostheses List reform activities.....	8
Background discussions by the BSRIWG	9
Strengths of the current framework.....	9
Issues with the current framework	10
BSRIWG discussions of possible approaches to setting and reviewing PL benefits	14
Purpose of the Prostheses List.....	14
Criteria for inclusion on the Prostheses List.....	14
Grouping schemes on the Prostheses List.....	15
Setting Prostheses List benefits.....	16
Reviewing Prostheses List benefits	26
Infrastructure to support the Prostheses List.....	29
Other relevant considerations	30
Revised assessment pathways for prostheses list applications	30
Harmonisation of government health technology assessment methods and processes	31
Use of appropriate data sources	32
Encouraging innovation and competition	32
Possible risk sharing arrangements	33
Proposed options for a revised framework for setting and reviewing PL benefits	33
Background to the options	33
Over-arching principles behind the proposed options	35
Characteristics of the options.....	36
Implications of each option	37
Appendix 1 Membership and Terms of Reference of the BSRIWG	51

EXECUTIVE SUMMARY

This report describes discussions by the Prostheses List Revised Benefit Setting & Review Framework Industry Working Group (BSRIWG). Building on these discussions and the outcomes of other reviews, this report also presents three options for a revised framework for setting and reviewing private health insurance benefits for medical devices listed on the Prostheses List (PL). The BSRIWG recommend that following publication of this report there be further public consultation and detailed and transparent examination of any preferred reform model (noting that a hybrid model might emerge during the broader consultation phase).

The BSRIWG is a multi-stakeholder group comprised of representatives from consumer organisations, private hospital providers, private health insurers, medical device manufacturers, reimbursement consultants, the Independent Hospital Pricing Authority (IHPA), and the Commonwealth Department of Health, chaired by Emeritus Professor Terry Campbell AM, the Chair of the Prostheses List Advisory Committee.

The BSRIWG met on eight occasions between April 2018 and February 2020. Discussions at these meetings were informed by earlier relevant considerations of prostheses benefits in the Australian context. The role of the BSRIWG has been to develop options for a revised framework for benefit setting and benefit review, reflecting use of health technology assessment (HTA) including evaluation of value, cost-effectiveness and innovation, use of post-market review, and the operation of competitive markets in the Australian context. This report describes the advantages and disadvantages of different benefit setting models for prostheses in the context of the Australian health system and proposes options for a revised PL framework that seek to:

1. promote the sustainability of privately insured healthcare to help maintain the affordability of private health insurance for all Australians,
2. minimise patient out-of-pocket costs, thereby protecting the value proposition of private health insurance,
3. preserve patient access to the device recommended by their doctor, and
4. support a viable, innovative and diverse medical technology sector in Australia.

The options outlined in this report were developed by the Menzies School for Health Policy, University of Sydney, and build upon discussions held during the BSRIWG meetings and the outcomes of previous reviews of PL arrangements. Options were presented to the BSRIWG at what was to be its penultimate meeting in February 2020, after which members were invited to provide additional feedback or commentary on the report. That feedback has been included in this report. Because of COVID-19, the final BSRIWG meeting did not proceed and timeframes for finalising the report were extended. BSRIWG members did not reach consensus on the reform options, nor did they have opportunity to identify their preferred options.

The options outlined in this report reflect a continuum from **moderate reform of current PL arrangements** (Option A), through **extensive reform of current PL arrangements** (Option B), to a **transition to a DRG model** (Option C).

Option A would represent a continuation of the current grouping structures on the PL, based predominantly on product characteristics (but with the extension of the PL criteria to allow the listing of non-implanted devices with a therapeutic purpose), but with fewer listed items. Under this option, assessment of devices could occur via one of three application pathways: an Abbreviated assessment undertaken by Departmental staff; a fit-for-purpose HTA pathway via PLAC; or a full HTA pathway via

MSAC and PLAC. PLAC and the CAGs would be retained. The additional Departmental resourcing required to support this option is substantial and would be funded via cost-recovery arrangements.

Under Option B devices would be included and grouped on the PL according to therapeutic procedure. PL benefits would be paid for the collection of medical devices and device components used during a single procedure on an individual patient, rather than for individual devices or device components (e.g. all of the orthopaedic devices and instruments required to repair a femur, or an implanted cardiac device with all of its associated leads, battery etc). As for Option A, implanted and non-implanted devices would be allowed, and the three assessment pathways would be available. Under this option it is anticipated that the time to market for products that qualify for the abbreviated pathway would be greatly expedited: once the TGA approves the specific uses of a device it could be immediately added to the corresponding use categories on the re-structured PL. As for Option A, PLAC and the CAGs would be retained. The additional Departmental resourcing required to support this option would be similar to Option A and would also be funded via cost-recovery arrangements.

Under Option C the PL would be replaced by a DRG grouping model whereby prostheses are grouped into existing and possibly new private sector DRGs and a private health insurance benefit set for the prostheses component of each DRG (noting that some aspects of the PL might be retained, such as a list for a high-unit cost, novel technologies). As the PL would largely be replaced, theoretically there would be no limit on the types of prostheses that could be allowable within a single private DRG, as long as the treating doctor deemed them clinically appropriate. It is proposed that the processes for administering the private DRG model would be undertaken by IHPA. There would be no ongoing role for PLAC or the CAGs. A key part of the planning for implementation of this option would be confirming the resourcing required for IHPA to take on this role.

These implications of adopting each option are discussed in terms of:

- The resources needed within the Department and/or IHPA to administer the arrangements
- How the costs to administer the arrangement might be covered
- How innovation would be recognised
- Access to new health technologies
- Steps required for transition to the new arrangements

The members of the BSRIWG expressed different preferences for the three options. **Whilst all members of the BSRIWG supported individual elements of each option, no consensus was reached about a preferred option.**

Members of the BSRIWG have identified the need for further broad consultation on the options presented in this report, both in relation to design and implementation. In keeping with its Terms of Reference but with the caveats outlined, the BSRIWG present this report to the Minister for Health and the Chair of the Medical Technology Association of Australia.

INTRODUCTION

PURPOSE OF THE PROSTHESES LIST

The stated role of the Prostheses List (PL) is to ensure that privately insured Australians have access to clinically effective prostheses¹ that meet their health care needs. However, it should be noted that the overall purpose of the Prostheses List is not defined in legislation and instead decisions about device listings are made with reference to listing criteria set out in guidance documents (see below).

Whilst the Therapeutic Goods Administration (TGA) assesses prostheses for clinical effectiveness and safety, it is the Prostheses List Advisory Committee (PLAC) that determines whether (and how) TGA-approved prostheses should be included on the PL and sets the benefits to be paid for them.

The PL benefit is the price paid by private health insurers to hospital providers for prostheses provided to privately insured patients as part of an episode of hospital treatment or hospital-substitute treatment. The treatment can be delivered to a private patient in a private or public hospital. The intention of the PL arrangements is that the benefits paid by insurers are relative to clinical effectiveness.

Important features of the PL are that it is seen as a mechanism for providing patients and doctors with access to a choice of prostheses at a price that means patients have no out-of-pocket expenses for their prosthesis². As such, the PL functions to provide privately insured patients with guaranteed coverage for the prostheses recommended by their doctor³. Whilst an assessment of private health insurance arrangements in Australia is beyond the scope of the current report, the MTAA and others assert that these features of the PL (doctor choice of device, and no patient out-of-pocket expenses for medical devices) are a component of the current value proposition of private health insurance.

CRITERIA FOR INCLUSION ON THE PROSTHESES LIST

Under the *Private Health Insurance Act 2007* (the PHI Act), private health insurers are required to pay benefits for prostheses that are included on the PL. The PL arrangements are set out in Division 72 of the PHI Act and the Private Health Insurance (Prostheses) Rules (the Prostheses Rules).

The PL is the schedule to the Prostheses Rules and is in three parts:

- **Part A** – prostheses that are used as part of hospital or hospital-substitute treatment where a Medicare benefit must be paid to the doctor for the procedure performed. The device must be surgically implanted or enable another device to be implanted or allow an implant to continue to function after surgery. The types of prostheses currently on Part A of the PL include (but are not limited to): hip, knee and other joint replacement devices; cardiac implantable electronic devices such as pacemakers and defibrillators; cardiac stents; vascular stents and grafts; heart valves; staples, sutures, and wound glue, and the devices used to deliver them during a surgical procedure.
- **Part B** – human tissue products that are substantially derived from human tissue where the tissue has been subject to processing or treatments, and whose supply (however described, including trade, sell, give or gift) is governed by state or territory law. The types of prostheses currently on Part B of the PL include: whole bones and bone fragments; corneas; skin grafts; and heart valves.

¹ The term prosthesis should be taken to mean medical device, as per the current criteria of the Prostheses List

² The requirement for no patient out-of-pocket expenses for prostheses was introduced in response the HTA Review 2009.

³ Public patients are provided with prostheses via activity-based funding arrangements, where the prices paid for prostheses are one component of a diagnosis-related episode of hospital care.

- **Part C** – medical devices that do not meet the criteria for Part A but the Minister for Health considers suitable for benefit payments by private health insurers. Devices listed in Part C of the PL currently include insulin infusion pumps, implantable cardiac event recorders, cardiac home/remote monitoring systems, cardiac ablation catheters, mapping catheters for cardiac ablation and patches for cardiac ablation.

Devices such as external limb prosthetics, external breast prostheses, or implants used solely for cosmetic purposes are not eligible for the PL.

The PL arrangements currently describe a prosthesis as an artificial substitute or replacement body part attached or applied to the body to replace a missing part. This definition encompasses two features for prostheses on the PL: (i) they must be implanted or remain within the body, and (ii) they must have a therapeutic purpose. Both of these aspects of the PL criteria were discussed by the BSRIWG (see below).

PROSTHESES LIST GROUPING STRUCTURE

In addition to the three Parts described above, the PL is divided into several **categories** of prostheses. For Part A these categories are currently: cardiac; cardiothoracic; hip; knee; ophthalmic; specialist orthopaedic; spinal; urogenital; vascular; ear, nose and throat; neurosurgical; plastic and reconstructive; and general and miscellaneous (prostheses not included in other categories). For Part B the categories are currently: cardiothoracic; ophthalmic; orthopaedic; and dermatologic⁴. For Part C the prostheses currently listed fall into the following categories: general and miscellaneous; cardiac; and cardiothoracic.

Within categories, the intention is that products are grouped according to similar clinical effectiveness. The 'grouping' refers to the full classification of a prosthesis on the PL, including category, subcategory, group and subgroup, which are identified numerically. Some prostheses also have alphabetical suffixes or descriptive text to designate additional features. Products can be listed as single items or as component parts of 'product systems'.

At the start of 2020 there was a total of 11,655 billing codes on the PL⁵: 10,826 on Part A; 771 on Part B; and 58 on Part C. Each code can list one or more items (prostheses) underneath it and may be billed one or more times for each episode of care. These codes and the items that sit underneath are organised into more than 1,700 unique groupings.

SETTING PROSTHESES LIST BENEFITS

Each grouping of products on the PL has a single group benefit, however groups and subgroups of products may be differentiated at the suffix level (i.e. the addition of a suffix may result in a different benefit). Sponsors can accept the group benefit, choose to list at a lower benefit or choose not to list the product. For products implanted into privately insured patients in public hospitals, insurers are required to pay the group benefit or the patient's liability to the hospital for the prosthesis, whichever is the lesser amount. However, standard practice seems to be to bill up to the benefit, although some public hospitals have arrangements where they bill less than the PL amount for private patients.

Under the current framework sponsors submit an application or amendment for a product listing with a proposed PL benefit. Sponsors are asked to provide sufficient information to justify the proposed benefit – usually via description of the similarities and differences between the new product and other products in a relevant group or subgroup. The proposed groupings and subgroupings are reviewed via a process of clinical assessment by the relevant Clinical Advisory Group (CAG) or by the Panel of

⁴ The grouping structure of Part B is under review at the time of writing.

⁵ Prostheses List accessed 13 January 2020

Clinical Experts (the Panel; see section below for more details on the infrastructure to support the PL)). Prostheses are then assessed by PLAC to determine their comparative clinical effectiveness and PLAC sets the benefit to be paid.

In response to the Doyle Review 2007 and the HTA Review 2009, the Government determined that negotiations of benefits for individual prostheses should cease and that a single benefit level should be established for all prostheses within a particular group, and that these groups should be established on the basis of similar clinical effectiveness. Since then, items which PLAC assess as providing similar clinical effectiveness to comparator items on the PL are listed in the same group with the same benefit applied. Items that PLAC assess as having superior clinical outcomes may have a higher benefit and will be assigned to different group to differentiate them from their comparator.

A consequence of this approach (creating new groups to reflect superior clinical outcomes) has been the creation of more than 1,700 possible unique groupings of products (see above). The MTAA view is that this is an unintended consequence of identifying clinical differences between devices, whilst some other members of the BSRIWG view it as an effective resumption of negotiating benefits for individual prostheses, which runs contrary to the intentions of Government.

Finally, whilst the setting of benefits by PLAC for prostheses seeking a higher benefit on the PL has been based on the available evidence, clinical advice from the CAGs or the Panel, and the collective judgement of the committee about relative cost and effectiveness, it has not generally been based on a formal assessment of comparative cost-effectiveness using HTA methods. There have been occasions where MSAC have provided advice to PLAC regarding a cost-effective price for a first-in-class prostheses⁶, but until recently PLAC has not consistently applied HTA methods to inform the setting of PL benefits.

REVIEWING PROSTHESES LIST BENEFITS

The benefits paid for devices on the PL are not regularly reviewed. In general, once items are listed on the PL there has been no structured mechanism for regularly reviewing the benefits paid for these items. The PL has been criticised as having a 'set and forget mode'⁷.

In February 2017, in response to recommendations by an earlier Industry Working Group⁸ the Government reduced the minimum benefit amount paid for four categories of prostheses on the PL: cardiac devices (reduced by 10%); intraocular lens (reduced by 10%); hip replacement joints (reduced by 7.5%); and knee replacement joints (reduced by 7.5%).

In October 2017, the Government entered into an Agreement with the MTAA that implemented a series of benefit reductions across the PL between February 2018 and February 2020.

INFRASTRUCTURE TO SUPPORT THE PROSTHESES LIST

The PL is administered by the Department of Health assisted by the PLAC, with expert clinical advice provided to PLAC by a number of CAGs and the Panel. The size and composition of PLAC is decided in consultation with the Minister for Health, with members drawn from a wide range of experts and

⁶ Please see the Public Summary Document for Transcatheter Aortic Valve Implantation (TAVI) via transfemoral or transapical delivery (<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1361.2-public>) and for transcatheter occlusion of the left atrial appendage for patients with non-valvular atrial fibrillation (<http://www.msac.gov.au/internet/msac/publishing.nsf/Content/1347.1-public>)

⁷ Senate Inquiry into Price regulation associated with the Prostheses List Framework (2017)

⁸ Industry Working Group on Private Health Insurance Prostheses Reform (2016)

stakeholder advisers⁹. Membership of PLAC is currently comprised of an independent Chair and 16 members – individuals with expertise in health technology assessment, specialist surgery/interventional work, health economics, or consumer issues, and representatives of the private health insurance industry, private hospital providers, and medical technology manufacturers.

The CAGs function as sub-committees of PLAC. Each CAG includes a Chair and individuals with contemporary subject matter expertise, additional skills identified by the PLAC, and an (unlisted) representative from the medical devices industry as an adviser¹⁰. There are eight CAGs that cover the following clinical areas: Cardiac prostheses; Cardiothoracic prostheses; Hip prostheses; Knee prostheses; Ophthalmic prostheses; Specialist Orthopaedic prostheses; Spinal prostheses; and Vascular prostheses. Each CAG varies in size from three to thirteen members, with a total of 48 individuals across all CAGs.

The Panel also advises PLAC. It consists of at least two clinical experts from each sub-speciality of listed prostheses. The categories of the PL covered by the clinical experts are: Ear, Nose and Throat; General Miscellaneous; Neurosurgical; Plastic and Reconstructive; and Urogenital. There are currently thirty-one members of the Panel¹¹.

The primary role of the CAGs and the Panel is to assess the clinical functionality and effectiveness of medical devices being considered for listing on the PL. These assessments inform the CAG/Panel advice to the PLAC and the department on the suitability of listing a device. The CAGs and the Panel have also advised on the appropriate classification and on eligibility for listing against the listing criteria.

PLAC meets face to face four times per year, with some meetings held over two days. Each CAG generally meets three times year, face to face or via teleconference. All of the secretariat support for these committees and subcommittees is provided by the Department.

All applications for the PL (new listings, amendments, or deletions) are made via an online portal, the Prostheses List Management System (PLMS). This portal is currently monitored and maintained by the Prostheses Section of the Department and is in the process of being assessed for possible migration to a centrally managed web platform (the Health Products Portal).

CURRENT PROSTHESES LIST REFORM ACTIVITIES

The Revised Benefit Setting and Review Framework Industry Working Group (BSRIWG) was established under the agreement between the Commonwealth Government and the Medical Technology Association of Australia (MTAA), referred to herein as ‘the MTAA Agreement’¹². The role of the BSRIWG has been to develop a revised framework for benefit setting and benefit review, reflecting use of health technology assessment (HTA) including evaluation of value, cost-effectiveness and innovation, use of post-market review, and the operation of competitive markets in the Australian context. The membership and Terms of Reference of the BSRIWG are provided in Appendix 1. The main output of the BSRIWG is the provision of the current report to the Minister for Health and MTAA Chairman.

⁹ The current membership and Terms of Reference for PLAC are available at <https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-about-PLAC>

¹⁰ The current membership and Terms of Reference for the CAGs are available at <https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-about-CAG>

¹¹ The current membership and Terms of Reference for the Panel of Clinical Experts are available at <https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-about-clinical-experts>

¹² A link to the MTAA agreement is available at <https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-PLAC>

Under the MTAA Agreement a second, concurrent, working group was established, the Quality of Information and Guidance Industry Working Group (QIGIWG). The QIGIWG has been following a workplan to explore revisions to the PL application processes and the technical guidance provided in the PL Guide. Together, the BSRIWG and the QIGIWG are undertaking a body of work that intends to:

1. Support sector stability and sustainability
2. Reduce the time to market for medical devices
3. Ensure Australian patients have access to safe, effective, and cost effective innovative medical devices in the private sector
4. Improve the transparency and efficiency of the PL arrangements
5. Recognise superior clinical performance
6. Support Australian medical technology innovation

Whilst each working group has its own Terms of Reference and different membership, there has been overlap in the matters discussed by the BSRIWG and the QIGIWG. This is to be expected given the inter-connectedness of the current PL arrangements and the intentions of the MTAA Agreement.

The MTAA Agreement recognises that the current framework for setting benefits for devices on the PL is not sustainable. The current reform activities are required to determine a new framework for setting and reviewing prostheses benefits that appropriately values technology innovation within the Australian private health system but does so in a way that ensures long-term efficient pricing of medical devices within the sector.

BACKGROUND DISCUSSIONS BY THE BSRIWG

STRENGTHS OF THE CURRENT FRAMEWORK

Explicit recognition of clinical differences

It has been argued that the PL is “necessary and desirable, particularly given the complex system in which prostheses are selected, purchased, paid for and reimbursed when a patient is privately insured”¹³. It was acknowledged by all members of the BSRIWG that the current framework provides flexibility to differentiate between product groups/sub-groups, is compatible with the incorporation of new and cost-effective technologies and recognises improvements in value.

Patient choice of healthcare

It is the view of many members of the BSRIWG that one of the key value propositions of private health insurance in general, and one of the main drivers for individuals choosing to pay for PHI is the desire to receive a higher standard of care with shorter waiting times and to be able to choose their doctor. Most members of the BSRIWG were of the view that patients assume that in the private sector the doctor, not the insurer or the hospital provider, are at the centre of clinical decision making. In other words, patients indirectly value the PL because it allows their doctor to choose the most appropriate medical device(s) on their behalf.

¹³ Senate Inquiry into Price regulation associated with the Prostheses List Framework (2017); point 4.5

Pricing transparency

Whilst payment arrangements between manufacturers, insurers and providers are generally opaque (see below for more discussion), the PL does provide transparent pricing for medical devices that are on the PL.

No patient out-of-pocket expenses

All members of the BSRIWG agreed that a key strength of the PL is that provides access to a range of clinically useful prostheses with no patient out-of-pocket expenses. Current PL arrangements have ensured that all (appropriately) privately insured patients have access to prostheses on the PL regardless of other commercial arrangements that exist between insurers and hospitals.

Incorporation of expert clinical input

Another strength of the current PL arrangements is that since 2005 the perspective of clinicians is now an integral part of the assessment process, via the CAGs and the Panel of Clinical Experts. It is worth noting that the importance of this clinical input continues to be recognised within the fit-for-purpose assessment framework that is proposed for the PL (see below).

ISSUES WITH THE CURRENT FRAMEWORK

Issues with the current framework for setting and reviewing benefits for the PL were discussed by the BSRIWG, and have been articulated by others, most notably:

- *Review of the Prostheses Listing Arrangements* (Doyle Review 2007)
- *The Review of Health Technology Assessment in Australia 2009* (HTA Review 2009)
- *Performance of Public and Private Hospital Systems Research Report 2009* (Productivity Commission, 2009)
- *The Review of Medicines and Medical Device Regulation 2015* (Sansom Review)
- *The Industry Working Group on Private Health Insurance Prostheses Reform 2016* (IWG 2016), and
- *Prostheses Benefit Setting Framework: Comparative analysis of benefit setting models 2017* (Clarke 2017).
- *Senate Community Affairs Reference Committee: Price regulation associated with the Prostheses List Framework 2017* (Senate Inquiry)

As noted most recently in the report of the Senate Inquiry¹⁴:

“the Prostheses List Framework has been subject to a number of reviews since its introduction in 1985. Successive reviews have consistently raised similar issues suggesting there are a number of challenges for reform. However, while the inquiry has shown that there is general support for reform, there is little agreement on the areas which require reform and how this should be achieved. The absence of agreement may be a symptom of both a segregated system where stakeholders have limited interaction with each other and a system which lacks transparency”.

¹⁴ Senate Inquiry into Price regulation associated with the Prostheses List Framework (2017); Points 2.1 and 2.2

The history of the establishment of the PL and previous attempts to reform the structure of the List and the benefits paid for devices is detailed in the report of the Senate Inquiry¹⁵.

Different pricing of prostheses between the public and private sectors

A key issue with the current PL framework is the observation that medical devices tend to have higher pricing in the Australian private sector when compared to the Australian public sector. As further noted by the Senate Inquiry:

“in many instances the minimum benefit amount of a prosthesis listed on the PL and paid by private health insurers is significantly greater than the price paid by public hospitals for the same device and internationally.”

This was a position not dissimilar from that in a 2009 Productivity Commission report on the performance of public and private hospital systems, which suggested that *‘the cost of prostheses in public hospitals is considerably lower than in private hospitals’*. The current PL benefit-setting framework is likely to be contributing to this disparity in pricing between the two sectors.

It was a matter of debate within the BSRIWG whether higher prices and greater choice of prostheses in the private sector are associated with improved patient outcomes. A recent review of NJRR data found that the revision rates for total hip replacement for osteoarthritis and fractured neck of femur was higher in private hospitals than in public hospitals, but that this difference was not present when the comparison was restricted to the ten prostheses with the lowest revision rate.¹⁶ As noted by the review authors, the considerable variation seen in the revision rates between hospital sectors in Australia was largely due to differences in prosthesis selection. Some members of the BSRIWG interpreted the review findings as evidence that greater choice of hip prostheses in the private sector is not associated with superior outcomes. However, in a presentation to the BSRIWG, the AOA disputed this interpretation, arguing that differences in patient selection and surgeon experience confound the comparisons of outcomes for public versus private patients. No alternative sources of data were presented by BSRIWG members to support the view that higher prices and greater choice of prostheses in the private sector are associated with improved patient outcomes.

The sustainability of the private health care market, more broadly, has been the subject of many policy initiatives over the past three decades. Whilst discussion of the overall value proposition of private health insurance is outside the scope of the current report, it is recognised that the payments made for medical devices are a significant component of the total expenditure by patients and private health insurers in Australia. The Australian Government has stressed the importance of reforming the Prostheses List framework to put downward pressure on private health insurance premiums¹⁷.

One of the BSRIWG members (PHA) presented an analysis that they said shows that the benefits paid for medical devices in Australia are high by international standards. However, another BSRIWG member (MTAA) disagreed, stating that pricing comparisons are difficult and noting that there has been no independent verification of the methodology used by the PHA for this international comparison.

¹⁵ Senate Inquiry into Price regulation associated with the Prostheses List Framework (2017)

¹⁶ Harris et al. Outcomes of hip and knee replacement surgery in private and public hospitals in Australia. *ANZ J Surg* 89 (2019) 1417–1423. doi: 10.1111/ans.15154

¹⁷ Minister for Health and Sport, the Hon. Greg Hunt MP, Prostheses reforms to deliver better value for private health insurance (Media release), 4 May 2017 available at: <http://www.health.gov.au/internet/ministers/publishing.nsf/Content/health-mediarel-yr2017-hunt043.htm?OpenDocument&yr=2017&mth=05> (accessed Nov 2020).

Complex payment arrangements for medical devices within the private sector

Many sources of complexity need to be considered in the context of prostheses benefits reform in Australia. There is complexity at the level of the health system – with multiple levels of government responsible for different aspects of health care delivery and/or funding, multiple private providers, insurers, manufacturers, and physicians, and multiple pathways of care that involve both the public and private health sectors. There is complexity at the level of the patient in terms of demographic, anatomic and disease characteristics, with increasing numbers of patients with multiple co-morbidities, many receiving multiple treatments over time. And there is complexity at the level of the medical devices – whether it relates to the technical characteristics of the technology itself, or the interaction between the physician and device at the time of use within a procedure.

The consequences of all this complexity are that:

- i. there are very many stakeholders with an interest in prostheses benefit setting,
- ii. these stakeholders do not share the same views on prostheses benefit setting,
- iii. the payment systems between stakeholders are not transparent, and
- iv. the PL sits alongside other payment mechanisms used by hospitals and insurers to fund medical devices and the interaction between these is very unclear.

Whilst the remit of the BSRIWG was to focus on processes and mechanisms for setting benefits for devices on the PL, discussions of the group often captured broader issues regarding the commercial arrangements between manufacturers, insurers, and private hospital providers. It was clear in many of the discussions of the BSRIWG that opaque payment arrangements have resulted in uncertainty amongst BSRIWG members regarding who pays for what and under what circumstances.

However, as noted above, all members of the BSRIWG agreed that the PL provides a level of pricing transparency for devices on the PL that is not available for the broader array of payment arrangements between manufacturers, insurers and providers. Indeed, it is the view of the MTAA that pricing of medical devices in the private sector is more transparent than pricing of medical devices in the public sector, and that this is a direct consequence of the current PL arrangements.

The absence of competitive market interactions for medical devices in the private sector was cited as one of the reasons for the establishment of the MTAA Agreement. The lack of transparency in pricing arrangements, and the disparity in pricing between the private and public sectors mean that it is not possible to know if a truly competitive market¹⁸ exists for medical devices in the Australian private sector.

¹⁸ A fundamental tenet of health economics is that regardless of the country, the market for health care *in general* is imperfect: in the majority of cases the consumer (the patient) is unable to make a truly informed decision about the 'purchase' of their healthcare. This is due to a number of structural issues: the significant knowledge requirements to fully understand the implications of healthcare choices; the power imbalance between a doctor and patient; and the difficulty for patients to compare healthcare costs across clinicians and providers. In the case of the Australian private market for medical devices, further market imperfection arises because it is the doctor and the private hospital who make the purchasing decision for the device, but it is the patient and the private health insurer who bear the financial risk of that decision.

Oversight

The Department of Health representative on the BSRIWG noted on more than one occasion that whilst the Commonwealth Government is charged with administering the system of prostheses listing and benefit setting it has no role in compliance. This contrasts with role of the Commonwealth Government in benefit setting for medical services (via the MBS) and pharmaceuticals (via the PBS). In response to the question of oversight of the PL, the MTAA proposed in feedback to a draft of the current report that limitations on data sharing between insurers and the Commonwealth could be resolved via legislative change. However, it is not clear how this would constitute a formal compliance role and which entity should or would be best placed to assume such a role.

The resources required to administer the PL were raised at multiple BSRIWG meetings and have also been discussed in detail by the QIGIWG. Administration of the PL includes (but is not limited to): the processes employed to receive and assess individual applications for new listings and amendments to existing listings; secretariat support for PLAC and CAG meetings; maintenance of the PL; commissioning of external assessments; liaison with the TGA and the MSAC secretariat; and communication with sponsors. The Department of Health representative on the BSRIWG made it clear that the extent of administration is directly proportional to the size and complexity of the PL, and the framework for evaluating relative value-for-money for different devices. A more detailed description of the infrastructure required to support the PL is provided in a later section of this report.

Lack of clear understanding and agreement about the purpose and scope of the PL

Early meetings of the BSRIWG focused on specific benefit-setting approaches (see below), but during these meetings it became apparent that discussion was also required regarding the types of products that could be included in the PL. It also became clear that members had different interpretations or views regarding the purpose and scope of the PL. For example, BSRIWG members did not agree on the appropriateness of including 'consumable' items such as sutures and staples but excluding 'consumable' items such as the camera used for capsule endoscopy. There was disagreement regarding the extent to which the PL covers items which might be legitimately covered via other funding arrangements. However, whatever the proper scope of the PL there was agreement that the scope had increased over time and despite attempts to confine the scope through listing criteria contained in legislation and guidance documents, there are now multiple anomalies.

Consequently, later BSRIWG discussions acknowledged that any option for revising the mechanisms for setting and reviewing PL benefits needed to simultaneously consider the structure, size and scope of the PL. At later BSRIWG meetings, there was explicit discussion regarding the purpose of the PL, the criteria for listing, and the inter-relationship between benefit-setting approach(es) and the PL grouping structure. These discussions are summarised below.

In parallel, it became apparent to the QIGIWG that the approach to PL benefit-setting influences the PL application pathways, with expedited assessment possible for products that claim equivalent performance and seek an equivalent or lower PL benefit, and more considered assessment required for products that claim superior performance and seek a higher PL benefit.

Furthermore, the agreements reached by the QIGIWG to introduce HTA methods for some PL assessments (see *Harmonisation of government health technology assessment methods and process*, below) emphasised the need to ensure that the resources allocated to undertaking an assessment were commensurate with the likely impact (i.e. clinical benefits, harms, and/or cost) of the product should it be listed on the PL. This highlighted the inappropriateness of undertaking formal HTA on product components, rather than on whole products or product systems, which in turn, has implications for PL groups/subgroups.

BSRIWG DISCUSSIONS OF POSSIBLE APPROACHES TO SETTING AND REVIEWING PL BENEFITS

PURPOSE OF THE PROSTHESES LIST

The BSRIWG along with the QIGIWG agreed that the PL should have an over-arching statement of purpose and scope that would provide context for stakeholders and decision makers and inform the application of listing criteria to individual applications. The need for an agreed statement of purpose and scope recognises that listing decisions require an overall understanding of the goals of the PL arrangements and judgement about application of listing rules.

The BSRIWG supported the following factors as being important matters to take into account when making listing decisions for the PL:

1. The current scope of general cover under private health insurance (hospital versus hospital-substitute care)
2. Demonstration of clinical effectiveness and cost-effectiveness as a precursor to listing and benefit setting
3. Avoidance of duplicated payments (e.g. medical services that include diagnostics that are funded through the MBS and/or medicines that are funded through the PBS)
4. Recognition that the PL is not the only mechanism for funding medical devices (and other therapeutic products) that are used in hospital care, but the PL should complement other hospital funding so as to avoid gaps in funding.
5. Avoidance of perverse behaviours prompted by access to PHI benefits rather than pursuing more efficient care (e.g. hospital admission for diagnostic tests which are more appropriately rendered in the community)
6. Ensuring that privately insured patients are not exposed to out-of-pocket expenses for use of a device listed on the PL.

It was agreed that the overall purpose of the PL should be to provide privately insured Australian patients with access to beneficial and cost-effective medical devices used in a medical procedure, as part of an episode of hospital or hospital-substitute care. Details of the discussions regarding the criteria and scope of the PL are presented below.

CRITERIA FOR INCLUSION ON THE PROSTHESES LIST

Discussion by the BSRIWG¹⁹ included consideration of the types of devices that do not meet the current criteria for listing on Parts A or B of the PL. As noted earlier, such devices may be approved, under exceptional circumstances and at the discretion of the Minister for Health, for listing on Part C of the PL. The types of devices proposed by MTAA for an expanded scope of Part A of the PL were:

- i. non-implanted devices with a therapeutic purpose, such as cardiac ablation catheters²⁰
- ii. non-implanted devices with a diagnostic purpose, such as cardiac pressure wires and *in vitro* diagnostic devices (IVDs)²¹.

¹⁹ The MTAA presented a discussion paper that framed the BSRIWG discussion at Meeting #6

²⁰ Cardiac ablation catheters were listed on Part C of the Prostheses List in March 2019 for the management of atrial fibrillation

²¹ According to the TGA a medical device is an *in vitro* diagnostic medical device (IVD) if it is a reagent, calibrator, control material, kit, specimen receptacle, software, instrument, apparatus, equipment or system, whether used alone or in

The industry proposal to allow non-implantable medical devices on to Part A of the PL was accepted by all members of the BSRIWG. The BSRIWG agreed with the Senate Inquiry that the PL criterion for a medical device to be implanted is essentially a legacy of historical clinical innovation and does not reflect modern clinical or technological innovation and the trend towards minimally invasive interventional procedures and away from 'full' surgical procedures²². However, the BSRIWG members agreed that any expansion of the types of products allowable on the PL should only occur after all other aspects related to the current scope of the PL have been resolved.

In BSRIWG discussions it was noted that expanding the PL to include medical devices with a diagnostic purpose has the potential to dramatically increase the number of items on the List and PL outlays by insurers. In addition, it was noted by the Department of Health there are existing methods and processes for assessing such devices via MSAC, and there are existing payment mechanisms for such devices in the private health sector. The view of the MTAA was that the inclusion of medical devices with a diagnostic purpose would be limited to single use, high-cost devices for hospital use only. The countervailing view of the Department was that given most diagnostic services are provided in an ambulatory setting (e.g. catheters and contrast media used in diagnostic imaging), funding diagnostic devices through the PL risks creating perverse incentives to move patients from ambulatory to hospital settings.

It was proposed by the Department of Health that the PL should be limited to specific purpose, high cost medical devices where the specific intention of the associated medical procedure is to remedy pathology using the listed device (e.g. hip prostheses, cardiac ablation catheters). It was noted that this definition would exclude general, non-specific products used as an adjunct to surgical procedures (e.g. general use sutures, adhesives, haemostatic clips). The MTAA agreed that whilst a discussion is warranted regarding the types of products included on the PL, they were not supportive of the definition proposed by the Department.

A number of BSRIWG members noted that high-volume, low-cost items represent a significant proportion of PL expenditure, and if the Department's definition was adopted for the PL then alternative payment mechanisms would need to be agreed for the 'non-specific' devices that would no longer be eligible for inclusion on the PL. The MTAA voiced concerns that the removal of low-cost items from the PL may result in their replacement with higher cost items with potentially no additional value²³.

GROUPING SCHEMES ON THE PROSTHESES LIST

Whilst the BSRIWG did not explicitly discuss the current grouping arrangements for the PL, they did discuss possibilities for reducing the overall number of items on the PL – referred to by others as 'rationalisation'²⁴ – in addition to the administrative task of removing superseded or inactive items.

The report by Clarke et al 2017 proposed two options for reducing the number of items on the PL. The first of these options was removal of all 'low unit-cost' items below a specified monetary value. Clarke et al 2017 noted that the lowest minimum benefit for an item on the PL at the time of writing their

combination with other diagnostic goods for in vitro use. It must be intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body, solely or principally for the purpose of giving information about a physiological or pathological state, a congenital abnormality or to determine safety and compatibility with a potential recipient, or to monitor therapeutic measures. The definition of an IVD does not encompass products that are intended for general laboratory use that are not manufactured, sold or presented for use specifically as an IVD

²² Senate Inquiry into Price regulation associated with the Prostheses List Framework (2017)

²³ Although this risk would be mitigated by the requirement for new products to demonstrate cost-effectiveness for inclusion on the PL.

²⁴ Clarke 2017

report was \$7 and that approximately 23% of all items had a PL benefit of \$250 or less. These authors observed that these items (which include devices such as insulin infusion sets, ligating clips, ventilation tubes, orthopaedic fixations screws and plates, and neurosurgical and gastrostomy catheters) are likely to be used in multiple quantities in a single procedure, and may be used in high annual volumes at the hospital level.

The second option proposed in the Clarke 2017 report was the removal of low volume items (although a threshold for 'low volume' of utilisation was not suggested). The rationale for this proposal was the recognition that there is little opportunity for competition for such products in the Australian private health sector.

Both of these options were discussed by the BSRIWG, but neither option received majority support. A Review of all items in the General and Miscellaneous category of the PL was announced by the Department in November 2019²⁵ and is due to be completed in 2020. The General and Miscellaneous category contains many items that might not meet the Department-proposed revised scope of the PL – general use items (e.g. closure and haemostatic devices) although other “miscellaneous” items that do not readily sit in other categories (e.g. radio-isotopes and bowel incontinence devices) do meet the proposed scope. Many of the general use items are high volume and low unit-cost relative to more specialised implantable devices that appear in other categories.

SETTING PROSTHESES LIST BENEFITS

The Clarke 2017 report undertook a comparative analysis of benefit setting models, and judged the most feasible models for the PL to be:

- i. price disclosure;
- ii. national and/or international reference pricing; and
- iii. market-based tendering.

The Senate Inquiry identified mandatory price disclosure, value-based pricing, and reference pricing as benefit-setting mechanisms that have been adopted by the PBS. The Clarke 2017 report also discussed the potential role of HTA in setting benefits – and it was acknowledged this is the most-accepted form of value-based pricing, nationally and internationally.

The BSRIWG discussed each of the benefit setting models listed above²⁶. A description of each model together with a summary of the advantages, disadvantages/risks and barriers, for each model is presented in **Table 1**. Summaries of the BSRIWG discussions of each benefit setting model are provided after the table.

²⁵ See <https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-phicircular2019-68>

²⁶ The BSRIWG also discussed the current approach to determining Super Clinical Performance (SCP) designation for products on the Prostheses List. This is actually a post listing mechanism for benefit setting, and consequently is discussed elsewhere in this report.

Table 1 Summary of benefit setting models discussed by the BSRIWG

Description	Stated advantages	Stated disadvantages/ risks and barriers
Price disclosure		
<ul style="list-style-type: none"> • Retrospective market-based system. • Requires all sponsors to participate in ongoing regular disclosure cycles whereby all sales revenue, volumes sold, and types and value of incentives are disclosed to the Department. 	<ul style="list-style-type: none"> • Already in place for pharmaceuticals. • Allows for on-going benefit adjustment where traded prices differ from current benefits. • Prices disclosed would be actual trade prices regardless of the level of additional services included. 	<ul style="list-style-type: none"> • Implementation will require significant legislative changes and mandatory participation from all sponsors to reveal 'true' prices. • Limited information on the magnitude and extent of discounting. • A complete list of incentives would need to be developed. • Costs of implementation both on sponsors and PLAC are likely to be very high. • Cannot be used to set benefits for items with no or limited competition. • Would require the development of an audit function.
Reference Pricing		
<ul style="list-style-type: none"> • A regulatory benefit setting mechanism that bases benefits on prices from other markets both internationally and domestically (e.g. state-based purchasers for public hospitals). • Prices could potentially be obtained from the purchasers or the sponsors (the latter may be a form of price disclosure). 	<ul style="list-style-type: none"> • Used overseas in many countries for drug pricing and in Japan for device pricing. • Could be implemented largely within the existing PL framework. • Facilitates movement in benefits to reflect changes in exchange rates. • Rapid benefit adjustment is possible if large differences between external prices and existing benefits. 	<ul style="list-style-type: none"> • Difficulty in obtaining accurate reference prices outside Australia. • Cost of assessing variations to reference prices could be considerable for sponsors and PLAC. • May require adjustment of benefits to reflect additional costs in the Australian private market. • Requires PLAC to establish an evidence-based mechanism to adjust benefits.
Tendering (market-based)		
<ul style="list-style-type: none"> • A prospective market mechanism that allows manufacturers to set prices for their products through a tender process. • Benefits would need to be set to generate gaps (e.g. co-payments) for higher price devices and potentially rebates for lower price items. • Scope for using a tendering arrangement for setting benefits for new classes of devices when more than one sponsor applies for listing. 	<ul style="list-style-type: none"> • Increases transparency and information flows to patients and surgeons about the cost of devices. • If patients were paid rebates for lower cost devices it would assist them in paying for gaps for other services (e.g. on MBS items). • Could provide a way to set benefits for some new classes of items. 	<ul style="list-style-type: none"> • A new approach that has not been tried before for the PL, but which operates successfully in the public sector for devices and other products (e.g. NDSS). • Requires extensive infrastructure change to establish procurement systems and manage tenders. • Is expected to reduce choice of products in the private sector.
DRGs		
<ul style="list-style-type: none"> • Diagnosis related groups are a classification system that bundles 	<ul style="list-style-type: none"> • Easily applicable, relies on existing infrastructure and data. 	<ul style="list-style-type: none"> • Incomplete data (some barriers around getting day hospital data)

Description	Stated advantages	Stated disadvantages/ risks and barriers
<p>inpatient care for reimbursement purposes.</p> <ul style="list-style-type: none"> It bundles care based on diagnosis, procedure/intervention codes, and associated costs. 	<ul style="list-style-type: none"> Introduces a benchmark price (increased competition) and is centred on transparency and innovation. Used universally in the Australian public sector and increasingly in the Australian private sector Internationally accepted mechanism (including in the USA) to moderate health expenditure through efficiency gains. Established process through IHPA could be used to collect costings and clinical coding data to support ongoing price setting Established AR-DRG classifications already used in public and private hospitals. 	<ul style="list-style-type: none"> Time lags (getting data and rolling out updated DRG versions to hospitals) have the potential to restrict innovation. Limitations around validating data in private hospital settings, with cost weights not accurately reflecting true costs for private hospitals. Potential for clinical effectiveness of a device to be ignored as profit margin is the key indicator.
HTA		
<ul style="list-style-type: none"> Involves a range of methods and processes that use different types of evidence to assess the quality, safety, effectiveness and cost effectiveness of health product and health services, and its likely utilisation and budget impact within the health system. 	<ul style="list-style-type: none"> Directly links funding decisions for a health technology to the demonstration of acceptable cost-effectiveness Supports allocatively efficient funding decisions in a systematic and transparent way. Has the potential to minimise the use of harmful or ineffective technologies 	<ul style="list-style-type: none"> Challenges in generating high-quality evidence due to the characteristics of medical devices in general (e.g. double-blinding trials, user learning curves, short product lifecycles, low volume of use). Not an efficient mechanism to manage prices following the initial benefit setting (i.e. post-market reviews).
SCP		
<ul style="list-style-type: none"> Superior Clinical Performance (SCP) is a system that rewards well-established, high performing devices with a greater benefit. SCP can be seen as a method of incentivising better outcomes for patients rather than simply rewarding innovation. 	<ul style="list-style-type: none"> Sponsors are incentivised to keep older, but high performing devices in the market. Insurers have clarity regarding greater differentiation of products. Surgeons are encouraged to use better performing devices, which reduces the rates of revisions for patients. 	<ul style="list-style-type: none"> Training and support for older products may not be as widely available as for newer products. Does not incentivise innovation. For insurers has the disadvantage of increased upfront costs which may have an impact on premiums. Does not ensure that only superior products are used, as all other products continue to receive benefits.

Price disclosure

Price disclosure was discussed by the BSRIWG at meetings 1, 2 and 3. Discussions were facilitated by a presentation on PBS price disclosure arrangements, which were introduced to address pricing discrepancies between Australia and other countries for generic pharmaceuticals. It was noted that the introduction of PBS price disclosure arrangements required significant legislative changes, and

multiple adjustments over a period of ten years to enhance and accelerate the price reductions observed.

The BSRIWG identified the key steps that would be required for a price disclosure process:

1. Collection and submission of data on revenue, incentives and volumes of products sold,
2. Processing of data and calculation of a weighted average disclosed price,
3. Making a determination of the weighted average disclosed price,
4. Notifying stakeholders of the outcome,
5. Handling administrative disputes, and
6. Implementing changes in price as a result of disclosure.

The BSRIWG discussed the administrative requirements for implementing a price disclosure mechanism for prostheses, including legislative change, establishing a price disclosure data administration team, piloting the process in one or more targeted groups of prostheses, and running several rounds of disclosure to cover the large number of items on the PL.

Price disclosure may improve pricing transparency for prostheses, but transparency is not guaranteed given the differences in the market for prostheses versus the market for pharmaceuticals in Australia. Because the decision-maker (the clinician), the purchaser (the hospital), and the payer (the private insurer) are siloed, the extent to which suppliers (device manufacturer) will truly compete is unclear.

Furthermore, the extent of competition within a prosthesis product class varies greatly: it was stated that pharmaceuticals are more likely to have 'me-too' and generic versions than are devices²⁷. It was suggested that in order for price disclosure to achieve possible savings it should be focussed initially on high volume groups. If price disclosure is to achieve its stated goal it requires disclosure of all the sales practices employed by supplier (i.e. any monetary or non-monetary incentive offered to encourage a purchase). For prostheses this raised a range of questions around the definition of 'incentive' as many suppliers provide technical support and training, consumables and software alongside supply of a device, and these costs are typically factored into the price of the device.

The **advantages** of price disclosure noted by BSRIWG members were:

- Increased transparency of pricing for consumers, Government, providers, users and suppliers, potentially leading to increased confidence in the system.
- Increased transparency and fairness in the system as price disclosure ensures the benefit paid for a device is equated to the price value.
- Determines where the cost burden lies and aims to realign this.
- Can expose assumptions about price differentials resulting in more accurate pricing.
- Least disruptive solution for medical technologies.
- Higher competition could drive prices lower over time.
- Increased visibility resulting in a level playing field.
- From hospital point of view, pricing disclosure removes pricing discrepancies.
- Increased affordability based on transparency of discounts and incentives

The **disadvantages** of price disclosure noted by BSRIWG members were:

- Intensive to implement, the Department and industry will need to prepare to do it well.

²⁷ although the extent to which differences between devices are clinically meaningful is not often tested. In other words, devices may vary in their characteristics but yield similar health outcomes for patients.

- The costs to implement and cost savings are currently unknown and likely to be very high for all parties.
- Will require legislative change to encourage sponsors to disclose pricing
- Potential for additional bureaucracy and administrative burden.
- Price disclosure may not exert enough downward pressure to drive cost down.
- Does not consider HTA (clinical outcome) or economic values beyond pricing.
- May result in unintended consequences such as out of pocket costs or cost-shifting of incentives.
- Perceived risk that access to innovative technologies will be lost.
- PL context does not translate exactly (i.e. difficult to substitute like-for-like as with pharmaceutical generics).

Reference pricing

Reference pricing was discussed by the BSRIWG at meetings 1, 2 and 3. Discussions were facilitated by a pre-circulated document and a discussion paper prepared by the Department. Reference pricing is a mechanism to compare the price (or benefit) paid for a medical device in one market versus another market. For domestic reference pricing the markets would be in the same country (e.g. the Australian private health sector versus the Australian public health sector). For international reference pricing the market comparisons would be made across two or more countries. The BSRIWG also considered 'internal reference pricing' which was defined as setting benefits for a medical device relative to a comparable device in the same PL group.

The BSRIWG emphasised the importance of ensuring that references are only made between comparable products. Elements they felt need to be considered when defining reference markets are:

1. Inclusions: what is being supplied as part of the pricing and what is the defined end price?
2. Technical support and service models: what support and service functions are provided with the product? If support and service models are different, how should they be valued?
3. Incentives: How is the market influenced by incentives?
4. Range of choice: what is the offering in the wider market, or from within one manufacturer?
5. Procurement practices: how are the devices procured (e.g. clinician choice, volume or frequency of use)?
6. Geography: What are the logistical implications for the price (e.g. freight costs)?
7. Broader economic factors: How are wages, costs of living, inflation, tax, foreign exchange rates, or GDP influencing local prostheses pricing?
8. Market access cost: What are the costs (time and resources) with bringing products to market, and the ongoing business costs (including TGA, PLAC and MSAC processes and activities, ongoing surveillance and registry costs) to maintain products in the Australian market?
9. Funding models: How are prostheses funded in the health system (e.g., private health insurance, public funding, co-payment schemes).
10. Product identification and data accuracy: How comparable are datasets and what information can be used to identify products (e.g. Stock Keeping Unit versus PL grouping suffixes versus Universal Device Identifier)?

The BSRIWG suggested a number of steps that would need to be taken to apply reference pricing to PL benefit setting. These steps included: (i) revision and simplification of the PL classification system; (ii) if international reference pricing is to be used, identification of a small number of reference countries with similar healthcare systems and accessible national data; (iii) establishing a simple

approach for comparing prices, such as defining a benchmark around a median price, or only applying reference pricing to high-volume products; and (iv) transitioning to a reference pricing model after a pilot and staged roll-out of the new model.

Most of the issues raised by BSRIWG members related to the capability of developing an international reference pricing system for medical devices in Australia given a perceived lack of relevant local experience²⁸. There was concern that whilst reference pricing could lead to greater pricing transparency in an international context, defining appropriate international reference markets was considered to be problematic with no agreed methodology to adjust for differences between health system financing models. It was stated that even if a methodology could be established, if it resulted in prices that were unacceptably low to sponsors there was a risk that products would be withdrawn from the Australian market.

It was noted that many but not all of the concerns with international reference pricing could be overcome by using a domestic reference price. One issue that would remain for a domestic reference pricing model, is the impact that volume has on price: larger public hospitals are able to negotiate lower prices for medical devices than smaller private hospitals (hence the industry concern that domestic reference pricing would push private sector prices down to the levels the public sector can negotiate). Another key issue that would remain is the need for a price disclosure mechanism if public hospital prices are to be used as the reference, as public tender prices are not currently publicly available. This could be overcome by using IHPA as a data source for benchmarking classes of devices.

Finally, it was noted that despite the issues with international reference pricing, it may have merit as the methodological basis for a one-off review of the PL to identify 'outliers' and adjust benefits as needed.

The **advantages** of reference pricing noted by BSRIWG members were:

- Provides transparency, validation and verification of the Australian cost profile
- Puts the Australian private sector prices in context with other markets
- Feasible mechanism and not costly if international prices are disclosed as part of PL application and at set review intervals
- Feasible and likely to work (i.e. drive price reductions) because it provides transparency and a means for benchmarking
- Fits well within an HTA based system
- Allows a benchmark to be set for potential reductions achieved through a price disclosure mechanism, contributing to the sustainability of the private sector through more equal pricing
- Allows for accounting of variables and inputs to pricing (e.g. clinical support, R&D)

The **disadvantages** of reference pricing noted by BSRIWG members were:

- Unfair comparison – Foreign reference pricing is an unfair comparison to inappropriate markets
- Complex to implement – many variables to adjust for and consider – makes data validation challenging. Examples of variables include:
 - Difference in procurement of technology process
 - Mapping and identification of devices is difficult across multiple international systems
 - No known method to adjust for different markets
- No legal jurisdiction to compel 'full disclosure'

²⁸ Although there is considerable government and sponsor experience with reference pricing for pharmaceuticals in Australia.

- If benchmark is below competitive pricing this may lead to some products being taken off the market
- There may be increased costs and regulatory burden

Tendering

Tendering was discussed by the BSRIWG at meetings 1, 2, 3 and 4. Tendering is a prospective market mechanism that allows sponsors to set prices for their products through a tender process. It involves a competitive tender for classes of medical devices with similar characteristics and clinically equivalent outcomes. The advantage of procurement through a tendering process is that it gives priority to products that deliver these clinical outcomes at the lowest, most cost-effective price. The disadvantage of tendering is that it is challenging to administer and typically limits choice in products as individual suppliers negotiate greater market share in exchange for price reductions.

Tendering is already used for procurement of prostheses in the Australian public health system. For example, Health Purchasing Victoria (HPV) aims to 'improve the collective purchasing power of Victorian public health services and hospitals' through the procurement of health-related goods, services and equipment. HPV manages large-scale tenders and establish contracts for common-use products and services on behalf of the state. This model provides a practical approach to achieving collective buying power and realising the associated cost-savings for the health system.

It was noted that by leveraging existing tendering models there might be an opportunity to replicate the savings achieved in the public sector for the private sector. Tendering can improve competition through a bid environment and may or may not maintain clinician and consumer choice and deliver transparency of pricing.

The BSRIWG noted the following key considerations in establishing a national purchasing process for prostheses in private sector, to ensure that price-led competition is an effective benefit setting mechanism:

1. agreement that all products within a PL group/sub-group deliver clinically equivalent outcomes,
2. that there is more than one supplier within the same PL group/sub-group,
3. definition of what input costs are included in the tendered items (e.g. support services, associated consumables, freight).
4. which entity or entities will act as the originator(s) of the tender:
 - a. private hospitals (the current arrangement),
 - b. private health insurers, or
 - c. a national purchasing body.

A number of different tendering models were explored by the BSRIWG, but very few members of the BSRIWG expressed support for tendering in any form. If tendering was to occur, members were of the view that it would need to be managed via a national purchasing body such as the IHPA. The main concern voiced by many BSRIWG members is that tendering will limit choice in the private sector.

The **advantages** of tendering noted by BSRIWG members were:

- Reduced prices
 - Will introduce price competition to the system with the potential to drive lower prices
 - May create a more competitive environment
 - Seeks to use market forces to set/review prices
- Transparency

- Greater transparency of pricing
- Process
 - Can be simple, quick and certain
 - Ongoing process, not set and forget
- Prostheses quality
 - Could improve quality through tender specifications – limit to proven performers in mature technologies
 - Removes the need for some HTA for benefit setting²⁹

The **disadvantages** of tendering noted by BSRIWG members were:

- It is expected to limit choice
- May be difficult to determine groupings
- Does not capture competition in an ongoing dynamic natural setting and requires intervention on a regular basis (e.g. once every four years).
- Significantly increased administrative costs and challenges

Diagnosis related groups / Activity based funding

Australian Refined Diagnosis Related Groups (AR-DRGs) is a patient classification system, which provides a clinically meaningful way to relate the number and type of patients treated in a hospital to the resources required by the hospital. AR-DRGs group patients with similar diagnoses requiring similar hospital services. DRGs are used in public hospitals to determine hospital funding under Activity Based Funding (ABF) and are also used in the private sector by insurers. DRGs could be used in place of the PL to set the benefit paid to hospitals on the basis of the patient's diagnosis and procedures received.

It was noted by BSRIWG members that many countries, including the USA, have used this approach to integrate the cost of medical devices into the amounts paid for an episode of care. It was acknowledged that this can create incentives for providers to improve health outcomes, increase efficiency, and contain overall health expenditure.

DRGs could be used alongside other pricing mechanisms to determine the cost-weight for a DRG. Price disclosure is already a key mechanism in the public health system application of DRGs, and this would be expected to apply similarly in the private context. Over time, as data are collected for DRGs for private prosthesis use and pricing, this would be expected to inform the cost-weight for each episode of care.

One option proposed by one of the BSRIWG members (IHPA) was to use the DRG public funding amounts as a reference benchmark and each year a reduction from private PL benefits could be made by a defined percentage to eventually reach equivalence between the public and private sector benefits for prostheses (see the discussion of domestic reference pricing above). A critical consideration in using the DRG model as a reference is that in the public hospital system the majority of prostheses are priced through a tendering process. Using the public system DRG costs may be an appropriate starting point (due to existing processes to ensure AR-DRG data accuracy and validation), but there should be some other mechanism to determine what benefits for prostheses are appropriate for the private context. It was unclear to the BSRIWG how price differentials for medical devices between the public and private sectors are due to differences in utilisation (i.e. volume and range of products and patient selection).

²⁹ This could be viewed as negative or positive depending on the stakeholder perspective

Members of the BSRIWG also noted the potential need for additional DRGs beyond those available in the public sector. For example, lens procedures have only one public hospital AR-DRG code which may not adequately account for the use of differentially priced lenses (e.g. bifocal versus multifocal) in private hospitals.

The BSRIWG noted the following considerations in shifting to what would effectively be a 'bundled payment' for a package of care:

1. Validation of data: whilst there is an extensive dataset available for the public sector, the corresponding data from the private sector is incomplete.
2. Products not available in the public sector: it was asserted that many medical devices are only available in the private sector, and research is needed to understand whether these products would be captured by existing AR-DRG codes, and whether the amount paid for such devices within that DRG would be appropriate.
3. Derivation of DRG cost: the AR-DRG model applies a median value taking account of variations in length of stay. There may need to be a mechanism for differentially pricing the medical device component within the overall cost of each episode of care.
4. The role of HTA: it was noted that HTA could be used to inform private DRG costs, and that it would need to focus on the overall procedure rather than the device³⁰.
5. Rewarding innovation: it was noted that there are mechanisms within the public health system to reward the introduction of innovative technologies, and similar mechanisms should be explored for the private sector.

The **advantages** of DRGs noted by BSRIWG members were:

- Easily applicable - the infrastructure required for DRGs is already well established in Australian public and private hospitals, and is overseen by an independent body (IHPA).
- Technical efficiency through an average pricing mechanism
- Introduces a benchmark price and facilitates price competition
- Allows for fair and simple comparison to public hospital pricing, or international benchmarks

The **disadvantages** of DRGs noted by BSRIWG members were:

- Potential risk that a private hospital will not adopt a specific medical device or procedure if it is very high cost.
- Potential risk that the cheapest device would be used by private hospitals, regardless of relative clinical effectiveness, to maximise their margin
- May restrict innovation as it is unclear how new products are captured in a DRG model in a timely way.

Finally, as noted in the Clarke report, the application of DRGs could help alleviate the regulatory and administrative burden associated with 'consumable-like' products on the PL:

"Close to a quarter of the items on the Prostheses List have a benefit of less than \$250, this includes items such as infusion sets, clips, screws and catheters. These low-cost items are used in high volumes and while there could be some variation in use between procedures it is likely that over time stable patterns of utilisation will be observed at a hospital level for many of these items. In these circumstances there is a case for treating

³⁰ This is already the approach used by MSAC.

these like surgical consumables and incorporating the cost into a revised theatre band or Diagnosis Related Group (DRG) fee³¹

Health technology assessment

The role of health technology assessment (HTA) was discussed by the BSRIWG at meetings 2, 5 and 6. These discussions were facilitated by member presentations from Mr Paul Dale of MTAA, Conjoint Professor Eugene Salole for MTAA, and Dr Megan Keaney, Department of Health.

As stated by the Department of Health, HTA already plays a vital role in ensuring the Australian Governments' objective of delivering a safe, effective and efficient health care system. The purpose of HTA is to provide policy makers, funders, health professionals and health consumers with the necessary information to understand the benefits and comparative value of health technologies and procedures. This information is then used to inform policy, funding and clinical decisions, and assist with consumer decision-making.

The Australian Government cannot financially support every new health technology that comes onto the market, so it aims to direct government funding, in the form of subsidies, to health technologies that are clinically relevant, cost effective and safe. HTA processes and mechanisms provide a means by which new technologies can be assured and prioritised against existing health care interventions. HTA is commonly applied to pharmaceuticals (including vaccines), diagnostic tests, medical devices, surgically implanted prostheses, medical procedures and public health interventions.

The key questions that HTA aims to answer for each new health technology, in comparison to alternative interventions, are: is it safe, does it improve health outcomes, and is it cost effective? Assessment of health technologies therefore includes evaluation of the comparative harms and benefits of a health technology, using clinical evidence of patient safety, efficacy and clinical effectiveness, together with an understanding of the cause, origin and prevalence of disease and knowledge of best practice treatment pathways.

A well-performing HTA system will:

- facilitate patient access to cost-effective health technologies that improve health outcomes;
- minimise the use of technologies that are ineffective or harmful;
- contribute to value for money investments in health technology in the context of limited health care resources;
- keep pace with evolving technologies, clinical practices and HTA methodologies;
- provide clear information on processes, rules and outcomes to stakeholders; and
- ensure the system is designed to achieve these outcomes in the most timely, effective, efficient and targeted way.

Use of HTA processes and methods is well-established for informing public funding decisions via the Pharmaceutical Benefits Scheme (PBS), the National Immunisation Program (NIP), and the Medicare Benefits Schedule (MBS), and is evolving to inform public funding decisions for blood products via the National product List (NPL), and for highly specialised therapies via the National Health Reform Agreement (NHRA).

Proposed revisions to the PL application pathways to encompass fit-for-purpose HTA were presented to and discussed by the BSRIWG (these have been developed via QIGIWG and are discussed in

³¹ *Prostheses Benefit Setting Framework: Comparative analysis of benefit setting models 2017* (Clarke 2017).

more detail below). In discussing the proposal to introduce fit-for-purpose HTA for the assessment of medical devices, BSRIWG members emphasised the following:

1. importance of consistency in methods and clarity of evidence requirements whilst allowing for flexibility in assessment on a case-by-case basis,
2. importance of a consistent, structured process with a clear mechanism for review,
3. incorporation of more transparent feedback to applicants if the outcome of an HTA is not consistent with the original application made by a sponsor.

There was a general acceptance that HTA is the current standard for assessing value and that HTA is required for novel and high unit-cost devices. The BSRIWG stressed the importance of having alternative pathways for HTA and that HTA of medical devices needs to be fit-for-purpose. The BSRIWG also noted the different infrastructure they thought would be required to support the three proposed assessment pathways: CAGs and PLAC for the abbreviated pathways; CAGs, PLAC and an HTA assessor for the focused HTA pathway; and CAGs, PLAC and MSAC for the full HTA pathway. The views of the BSRIWG on this matter are different to those of the QIGIWG, who recognise that CAGs cannot be involved in the abbreviated pathway due to the expedited timeframe for assessments.³²

The **advantages** of HTA noted by BSRIWG members were that it:

- facilitates patient access to cost-effective health technologies that improve health outcomes,
- can minimise the use of technologies that are ineffective or harmful,
- informs investments in health technology by highlighting value for money in the context of limited health care resources, and
- incorporates an evidence-based appraisal of safety, clinical effectiveness and cost effectiveness

The **disadvantages** of HTA noted by BSRIWG members were that:

- double-blinded clinical trials are often not practicable for medical devices,
- the effectiveness of a medical device can be highly dependent on the skill of the clinician implanting or using it,
- medical devices have shorter product lifecycles than pharmaceuticals, with frequent incremental changes made to products over time (which can quickly make collected evidence obsolete),
- some medical devices have a very low volume of use which limits the quantity of evidence that can be collected, and
- HTA is not an efficient mechanism for reducing prices of a product after listing (i.e. post-market review).

REVIEWING PROSTHESES LIST BENEFITS

There was explicit discussion by the BSRIWG of only one model for reviewing benefits on the Prosthesis List – the determination of SCP (see below) – although the role of each of the benefit setting models described above were considered by the BSRIWG in the context of reviewing benefits.

As acknowledged previously by the Senate Inquiry, there are a number of existing post market review activities for medicines and medical services used by the Commonwealth which could be applied to medical devices. These include:

³² QIGIWG expects the required infrastructure to be: Departmental officers and the delegate for the abbreviated pathway; Departmental officers, CAGs/Panel, PLAC, HTA assessor, and the delegate for the focused HTA pathway; and Departmental officers, CAGs/Panel, PLAC, MSAC, HTA assessor, and the delegate for the full HTA pathway.

- Reviews with a focus on therapeutic purpose, such as the PBAC review of all PBS-listed medicines used to treat chronic obstructive pulmonary disease;
- Reviews with a focus on a specific health technology, such as the Department's current review of immunoglobulin across multiple indications;
- Monitoring of predicted versus actual utilisation of PBS-listed pharmaceuticals by the Drug Utilisation Subcommittee for PBAC;
- Monitoring of predicted versus actual utilisation of MBS-listed services by the Medicare Benefits Division for MSAC;
- The comprehensive program of work of the MBS Reviews Taskforce;

However, such reviews are not efficient for adjusting prices over time. Reviews are typically slow (12-18 months), expensive, difficult to scope, and tend to have protracted implementation timeframes. A number of PL reviews have been recommended by PLAC, but at the time of writing few have commenced, and revisions to the types of products or groups on the PL cannot be made before December 2021.³³

There was disagreement among BSRWIG members regarding who should bear the cost of prostheses benefit reviews: the MTAA was of the view that such costs should be funded as part of the support the Government provides to the PHI sector, whereas the Department was of the view that such costs should be recovered from industry (potentially including PHIs and hospital providers as well as medical device manufacturers).

Superior clinical performance

Superior Clinical Performance (SCP) was discussed by the BSRIWG at meetings 5 and 6. SCP relies on the availability of long-term clinical data and hence is only used for well-established implanted prostheses. It is a mechanism for linking superior performance (defined as greater than 95% prostheses survivorship relative to all prostheses) based on at least 10 years of clinical registry data. Whilst it is open to a range of medical devices in theory, in practice SCP has been used primarily to assign higher PL benefits to orthopaedic prostheses where performance data has been taken from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR). Prostheses that achieve SCP as assessed by both CAGs and PLAC are given a superior clinical performance suffix to indicate the SCP.

The BSRIWG noted that knowledge of superior performance of specific devices would be expected to encourage use of those devices, which should result in improved patient outcomes. However, whilst SCP works for a subset of devices where there is an appropriate clinical registry, it is unlikely to be feasible for all medical devices on the PL. In addition, SCP is essentially an HTA-based mechanism for reviewing prostheses benefits as it explicitly links pricing to comparative safety and effectiveness.

Furthermore, it has been noted that the SCP model raises the issue of how the prostheses benefit review mechanism should respond to evidence of *inferior* clinical performance for products that have not reached the threshold for removal from the market. The following point from the Clarke report is also noted:

³³ It is a condition of the MTAA Agreement that products cannot be removed from the PL during the life of the Agreement.

“If the concept of rewarding superior performance is accepted as a basis for setting benefits, it is difficult to see why products with inferior clinical performance (e.g. those with lower survivorship) should not be penalised by setting a lower benefit”.³⁴

The BSRIWG discussed how clinical performance could be incorporated into setting and reviewing PL benefits, acknowledging that such assessment had four potential conclusions:

1. Superiority: clinical evidence is consistent with a conclusion that a device is safer and/or more effective than comparable devices
2. Non-inferiority: clinical evidence is consistent with a conclusion that a device is no worse than other comparable devices in terms of safety and effectiveness
3. Inferiority: clinical evidence is consistent with a conclusion that a device is worse than other comparable devices in terms of safety or effectiveness.
4. Inconclusive: available evidence is insufficient to make a judgement regarding the comparative clinical performance of a device.

The **advantages** of SCP noted by BSRIWG members were:

- For clinicians:
 - Access to high performing devices
 - Sponsors keeping high performing devices on the market
 - Less need to create new instrument sets
- For insurers
 - Differentiation of products
 - Encourages surgeons to use better performing products
 - Benefits associated with decreased revisions
- For sponsors
 - May encourage sponsors to keep high-performing products on the market
 - Incentive for incremental improvement
 - Opportunity to increase market share
 - Small step towards value-based reimbursement
- For consumers
 - May see indirect benefits resulting from better performing prostheses available to surgeons

The **disadvantages** of SCP noted by BSRIWG members were:

- For clinicians:
 - Very little sponsor-provided training tends to be available for older systems – most sponsor-provided training is connected to new devices
 - May not advance innovation
- For insurers
 - Increased upfront costs – potential impact on premiums
- For sponsors

³⁴ *Prostheses Benefit Setting Framework: Comparative analysis of benefit setting models 2017* (Clarke 2017).

- May negatively impact suppliers of poorer performing products
- For consumers
 - Consumers do not have access to the PL and therefore SCP does not influence their choice
 - Does not ensure that better devices are being used

The BSRIWG acknowledged that while there may be a place for SCP, an alternative to the SCP mechanism is required for the majority of medical devices on the PL given the issues associated with the duration and nature of data required.

INFRASTRUCTURE TO SUPPORT THE PROSTHESES LIST

Over the years, stakeholders have consistently expressed concern about many aspects of the administration of the PL, and these concerns have in part prompted the current reform agenda. The concerns expressed by BSRIWG members include timeliness of processing applications, poor quality applications by sponsors, absence of evidence to support claims made by sponsors, inconsistency in advice between and within the CAGs, errors in assessments, and a lack of transparency with respect to listing decisions. These matters were discussed by the BSRIWG and responding to them formed the major part of the work of the QIGIWG (for more discussion of the proposed revised PL application pathways please see the following section).

As noted by the Department of Health, there are structural funding and governance issues that mean administration of the PL by the Department will continue to be problematic despite worthwhile process reforms. Unlike the PBS and the MBS, the Commonwealth government does not have a direct stake in PL arrangements. It does not receive or pay claims - hence it has no role nor legislative authority to manage claims processing or to ensure compliance (pre and post payment). In addition, it does not collect sufficiently granular data that would enable it to adjudicate disputes between insurers and hospitals or to undertake systematic compliance monitoring.

The Department observed that in their experience insurers, device companies and hospitals frequently look to the Department to resolve claims' payment disputes, which the Department is not tasked to do. On the other hand, these complaints also expose problematic listing decisions and misuse of the PL once items are listed.

The Department acknowledged that there are instances where the volume of applications (up to 700 per cycle) and the limited administrative resources of the Department have resulted in some applications receiving insufficient scrutiny. The Department and insurers voiced concerns that applicants have sought to exploit these administrative deficiencies to their commercial advantage. Indeed, disputes about listing decisions may come to notice from competitor companies that believe they have suffered commercial detriment as a result of an 'incorrect' listing or category change for a competitor's product. In other instances, there may be items that are incorrectly claimed by hospitals for reasons ranging from genuine mistakes (e.g. as a consequence of ambiguous rules) through to outright fraud. In this latter respect, the PL is like any other third-party payment system.

The Department brought to the attention of the BSRIWG the fact that they are not adequately resourced for any of the following activities: routine collection and analysis of PL data; monitoring usage; undertaking post market reviews (which is a desirable feature of any HTA-based system for assessment of value); reviewing disputed claims; or undertaking any systematic compliance.

The Department also queried whether it is desirable for government to undertake any of these activities, in what is essentially a private market. However, should the Department be given responsibility for these additional functions they are of the view that they would need to be sufficiently

resourced to do so. It is clear that even the revised PL processes that are already underway will require significant increased funding to enable full implementation.

OTHER RELEVANT CONSIDERATIONS

REVISED ASSESSMENT PATHWAYS FOR PROSTHESES LIST APPLICATIONS

Under the MTAA Agreement a second working group was established, the Quality of Information and Governance Industry Working Group (QIGIWG). This group has met six times between July 2018 and February 2020, including a joint meeting with the BSRIWG.

The QIGIWG was tasked with overseeing the review and update of the PL Guide and associated PL application forms, and the development of fit-for-purpose HTA pathways for the assessment of applications to the PL. The concept of a three-tiered approach to the assessment of devices seeking addition to Part A of the PL has been agreed, and the specific criteria and methods of assessment are being piloted by the Government.

The three assessment pathways that are likely to be implemented for Part A of the PL are as follows:

- **Abbreviated pathway:** a new pathway for lower-risk devices where the sponsor is seeking to have the device added to an existing functional group on the PL at the same or lower benefit to a comparator device already listed in that group. Assessments via this pathway would be largely administrative in nature, undertaken by Departmental officers on behalf of the Minister's delegate.
- **Focussed HTA pathway:** an expansion of the existing assessment pathways used by the PLAC to include the use of HTA evaluators to assess incremental value, as required, typically in cases where a higher benefit is sought for a lower-risk device relative to a comparator device on the PL. Assessments via this pathway would continue to rely on expert input from members of the CAGs and the Panel.
- **Full HTA pathway:** the existing assessment pathways used by the Medical Services Advisory Committee (MSAC) to evaluate the comparative effectiveness, safety, and cost-effectiveness of novel or innovative devices, typically but not always higher-risk devices, which may or may not require the establishment or modification of a Medicare Benefits Schedule (MBS) item. Assessment via this pathway would allow confirmation of PL grouping for a device by members of the CAGs or the Panel.

The PLAC has agreed on **four guiding principles for the assessment** of applications to list products on the PL:

1. Assess a single prosthesis based on its claimed impact(s) on health outcomes and cost with reference to one or more comparators.
2. Adopt the most efficient assessment pathway according to agreed Departmental triage criteria and whether or not one or more of the comparators is a prosthesis that is already included on the PL.
3. Undertake clinical and health economic assessments using approaches that are commensurate with the claimed impact(s) and that align with approaches taken to determine listings on the MBS.
4. Provide clear, high-quality advice to applicants in situations where the assessment of a prosthesis is not consistent with the impacts claimed by the applicant.

The advice and outputs from QIGIWG and PLAC have been considered by the BSRIWG and are incorporated in the options presented in the current report.

HARMONISATION OF GOVERNMENT HEALTH TECHNOLOGY ASSESSMENT METHODS AND PROCESSES

Efficient and effective HTA processes are crucial to supporting sustainable management of subsidised health technologies. Consistent application of evidence across Australian Government HTA processes is an important element in ensuring stakeholder confidence in the HTA framework by creating certainty in how these processes are implemented and their achieved outcome.

The entities that provide HTA advice to the Australian Government are: the Therapeutic Goods Administration (TGA); the Pharmaceutical Benefits Advisory Committee (PBAC); MSAC, and PLAC. These entities have complex and inter-dependent relationships. Each entity has discrete functions and responds to different policy needs.

The Australian Government HTA framework is supported by the TGA, MSAC, PBAC and PLAC through the following functions:

1. Assessment of the safety and efficacy of health technologies for market regulation to ensure that therapeutic goods are safe, perform as intended and are produced using appropriate quality controls before marketing approval is granted in Australia through the Australian Register of Therapeutic Goods (ARTG).
2. Appraisal of the comparative safety, clinical and cost effectiveness of health technologies which informs decisions about:
 - a. public funding of medical services (with or without a device), procedures and diagnostic technologies, pharmaceuticals and vaccines through the Medicare Benefits Schedule (MBS), the Pharmaceutical Benefits Scheme (PBS), the National Immunisation Program (NIP), and other appropriate funding mechanisms such as the National Product List (NPL) for blood products.
 - b. private health insurance reimbursement of prosthetic devices through the PL
 - c. post market surveillance of these health care interventions to inform ongoing decisions about the marketing approval of therapeutic goods or the reimbursement of health technologies that prove not to be safe, cost-effective, or do not perform as intended.

As described above, a three-tiered approach to the assessment of applications to Part A of the PL has been proposed by QIGIWG and is being piloted in 2020. These pathways represent the introduction of fit-for-purpose HTA for the first-time assessment of medical devices, and provide some of the framework for setting prostheses benefits:

- in the abbreviated pathway the benefit for devices with similar value are referenced to the benefits for comparable devices already on the PL;
- in the focussed HTA pathway PLAC would provide advice to the delegate regarding setting an appropriate benefit for a new device that reflects any demonstrated additional value for that device relative to similar devices on the PL; and
- in the full HTA pathway, MSAC would provide advice to PLAC and the delegate regarding setting an appropriate benefit for a new device that reflects any demonstrated additional value for that device relative to current standard of care within the health system (which may or may not include the use of devices on the PL).

As noted above, the adoption of HTA therefore provides a framework for estimating the value of medical devices. As will be detailed in the updated PL Guide the value of medical devices may arise

from safety, effectiveness, cost-effectiveness and/or efficiency gains. Importantly, whilst the HTA methods proposed for the PL are fit-for-purpose, they are based on the same fundamental principles of evaluation employed by MSAC. Sharing this methodological approach is expected to strengthen the link between PLAC and MSAC, and between PL listings and MBS items.

It should be noted that QIGIWG was advised by the Department that the Guidelines for the assessment of applications to MSAC (the 'MSAC Guidelines') are undergoing review and update at the time of writing the current report. An important aspect of the proposed revisions to the MSAC Guidelines is recognition of the potential for greater alignment between the methods and processes used by MSAC and PLAC. This alignment will support the second and third PLAC application pathways listed above and is expected to facilitate the flow of advice between the two committees as required.

There are opportunities for MSAC to provide advice to PLAC on a more regular basis - for example, every time an application to MSAC includes consideration of a specific medical device, the advice from MSAC to the Minister regarding the cost-effectiveness of the medical service could also include advice to PLAC regarding the cost-effective benefit for the device.

USE OF APPROPRIATE DATA SOURCES

The use of appropriate data sources was discussed on many occasions by the BSRIWG in the context of setting and reviewing prostheses benefits. The use of appropriate data to inform judgements regarding product equivalence or superiority falls within the remit of QIGIWG and is reflected in the currently proposed revisions to the PL Guide. In summary, the revised PL Guide provides greater clarity around the appropriate use and critical appraisal of observational data to support applications for listing on the PL. The revisions to the PL Guide recognise the place for non-RCT evidence in benefit setting, according to the clinical and/or economic claims being made by the sponsor, and whether the sponsor is making a claim of superior effectiveness or substantial similarity.

The BSRIWG also discussed the use of post-market data to inform reviews of benefits and the potential for longer term collection of outcomes data (e.g. via clinical registries) to increase, maintain or decrease benefits depending on the resulting cost-effectiveness. Consumers (including the consumer representative on the BSRIWG) have consistently advocated for the use of registries to monitor safety and performance. One of the ToR for the BSRIWG was the consideration of "practicable approaches for demonstrating the cost-benefit of devices". This was also addressed by QIGIWG via the three-tiered application pathways.

ENCOURAGING INNOVATION AND COMPETITION

It was noted during BSRIWG discussions that 'novel' does not necessarily mean better. Taking prosthetic joints as an example, AOANJRR data has demonstrated that patient outcomes have not improved from the use of new devices listed in the last 15 years and some new devices have performed worse than devices that have been on the market for some time. As noted above, devices with proven superior performance drive better outcomes for patients, and SCP is recognised as a method of incentivising these outcomes rather than rewarding innovation for the sake of innovation. Members of the QIGIWG confirmed that the availability of SCP had resulted in products remaining on the PL when the sponsor might have otherwise withdrawn them from the Australian market.

Most BSRIWG members agreed that adoption of an HTA framework for setting prostheses benefits is expected to encourage innovation. A fundamental principle of an HTA framework is that it provides an accepted methodology for the explicit recognition of value for new health technologies: allowing higher

(cost-effective) benefits to be set for devices that are shown to be associated with superior outcomes³⁵.

POSSIBLE RISK SHARING ARRANGEMENTS

The MTAA presented a position paper to the BSRIWG on risk sharing arrangements. In general, BSRIWG members agreed that risk-sharing was not appropriate or feasible for the PL but there may be some situations where it is warranted. The Department of Health noted that price-volume arrangements may be negotiated by the Department for specific health technologies, typically high-cost PBS-listed pharmaceuticals, and that such arrangements are usually between the Commonwealth and the sponsor of the health technology. It was not clear how the Department could negotiate risk-sharing arrangements between multiple private sector stakeholders for medical devices.

PROPOSED OPTIONS FOR A REVISED FRAMEWORK FOR SETTING AND REVIEWING PL BENEFITS

Building on the discussions of the BSRIWG and other reviews of the Prostheses List, the following options have been developed as alternative benefit setting and review mechanisms for the Prostheses List.

BACKGROUND TO THE OPTIONS

Purpose and scope of the PL

There was limited discussion by the BSRIWG as to whether the PL should be abolished – much of the discussion by the BSRIWG assumed the PL would be retained - but there was discussion about other approaches to funding (such as DRGs) that do not rely on listing and benefit setting for individual items within a system of defined eligibility criteria (e.g. the PL).

If the PL is to be retained and improved, then it is the near-consensus view of the BSRIWG and the QIGIWG that there needs to be a clear statement of purpose and scope for the PL. As noted above, it was agreed that ideally the overall purpose of the PL should be to provide privately insured Australian patients with access to beneficial and cost-effective medical devices used in a medical procedure, as part of an episode of hospital or hospital-substitute care, with no patient out-of-pocket expenses for listed devices. Most BSRIWG members supported the proposal that the PL should be limited to specific purpose, medical devices where the specific intention of the associated medical procedure is therapeutic (i.e. to remedy pathology) through use of the device, but the device is not required to be implanted.

The extent of the problems with the current PL arrangements have been well-documented by the BSRIWG and others, and the scale and complexity of the issues argue for an overhaul of the system. One option, Option C, envisions such an overhaul.

All three options recognise that the provision of medical devices within private hospitals and funded through private health insurance should operate within competitive markets and not rely fundamentally on government intervention, although it is acknowledged that Government has a role in setting quality

³⁵ A well-functioning HTA framework could also reward sponsors for investing in the collection of appropriate quality evidence: competitors could be required to subsequently demonstrate superiority or substantial equivalence to the first-to-PL product in order for their product to be listed.

use standards and promoting high value care so as to ensure that the private health sector remains viable.

Revising the criteria for the PL

It is recommended that a new definition of a “prosthesis” be developed and legislated. Other current prerequisites to listing of a device on the PL are that (i) the medical device must be used as part of a hospital or hospital-substitute procedure, (ii) the device has a current ARTG number and (iii) there is a relevant MBS item for the associated medical service. It is proposed that all three of these criteria are retained. It is further proposed that the second two criteria are strengthened as follows:

- a device on the PL must not be used outside its TGA-approved indication(s), or alternatively, specified restrictions to the PL be introduced, and
- the listing of the device on the PL refers to the specific MBS item or items that cover the medical procedure that has the intended purpose of inserting or using the listed device.

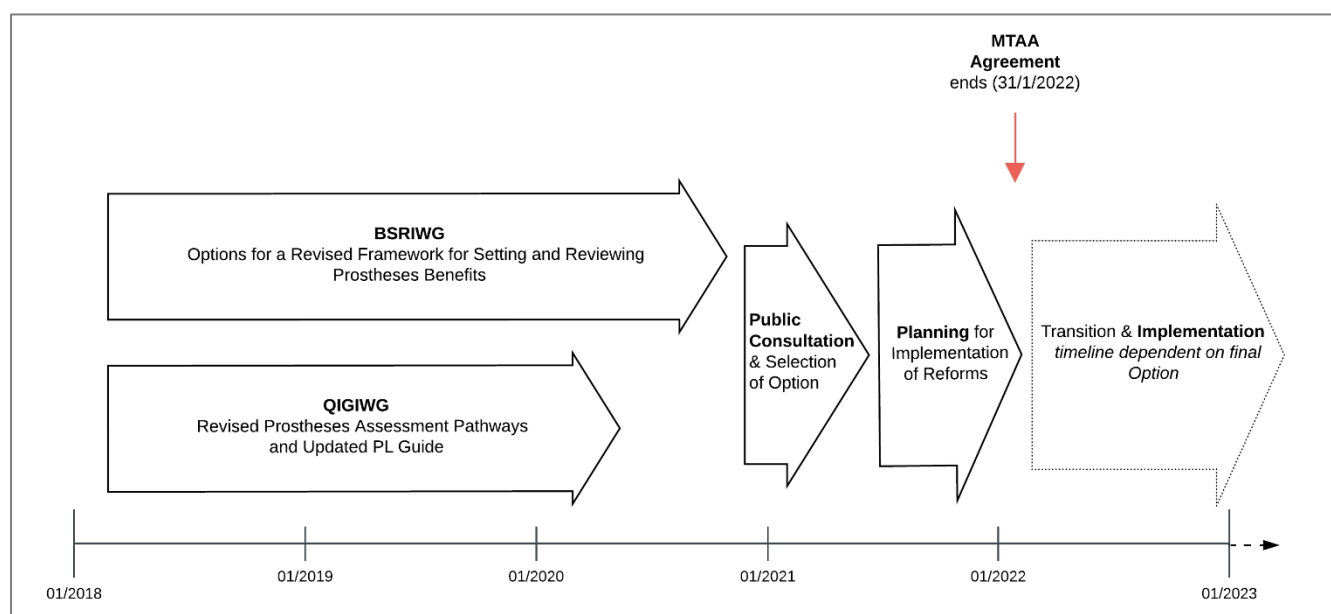
Bringing together the advice of the BSRIWG and QIGIWG

As noted in this report, the topics discussed by the BSRIWG frequently overlapped with topics discussed by the QIGIWG, and the inter-relationship between the advice arising from the two groups is clear: improvements to current PL arrangements require consideration of the criteria for listing on the PL, the methods for assessing the value of prostheses, and the processes used to set and review prostheses benefits. It is acknowledged that work still needs to be undertaken to bring together the advice from these two working groups before changes to the current PL arrangements can be implemented. An indicative timeline of these reform activities is shown in Figure 1 (excluding the impact of unknown delays as a consequence of the COVID-19 pandemic)

Based on the totality of discussions by the BSRIWG it is clear that no single pricing mechanism is appropriate or feasible for setting and reviewing medical device prices for privately insured patients, and that a hybrid model with multiple pricing mechanisms is likely to be required to meet all of the objectives of the MTAA Agreement.

Consequently, the BSRIWG is proposing options for a revised framework that are *independent* of specific pricing mechanisms. It is proposed that once an option has been selected the discussions of the BSRIWG (as captured herein) could inform later discussions regarding specific pricing mechanisms during the implementation planning stage.

Figure 1 Indicative timeline for selecting and implementing a revised framework for setting and reviewing prostheses benefits



OVER-ARCHING PRINCIPLES BEHIND THE PROPOSED OPTIONS

Improved administrative efficiency of prostheses arrangements

Members of the BSRIWG have identified a number of factors that they believe have contributed to inefficiencies with current PL arrangements³⁶, including the following:

- i. application pathways that are not commensurate with the risk associated with a prosthesis,
- ii. acceptance of poor quality or incomplete applications by sponsors,
- iii. lack of consistency in clinical advice from CAGs and decision-making by PLAC,
- iv. number of applications per cycle,
- v. total number of items and benefits included on the PL, and
- vi. complexity of the classification system and the uncertain reasons for differential benefits for like products.

Items (i) to (iii) have been directly addressed by the QIGIWG, resulting in a proposal to introduce three risk-based assessment pathways, and proposed revisions to the PL Guide to provide greater clarity to sponsors and the CAGs regarding assessment criteria for the PL.

Items (iv) and (v) are inter-related and are a reflection of the current structure of the PL which is based on product characteristics and allows prostheses benefits to be paid for individual devices and device components. The Department, who administers the PL, is of the view that rationalisation of the PL would greatly improve the efficiency of administering the PL arrangements. Options A and B include different approaches to such rationalisation of the PL that were proposed by the Department and discussed by the BSRIWG.

Transition to modern healthcare payment models that recognise innovation

The options for a revised framework proposed by the BSRIWG reflect international trends away from input-oriented payment systems that tend to reward over-use of health services, towards payment

³⁶ Not all members agree with all of these factors, but this list reflects the totality of views expressed across members.

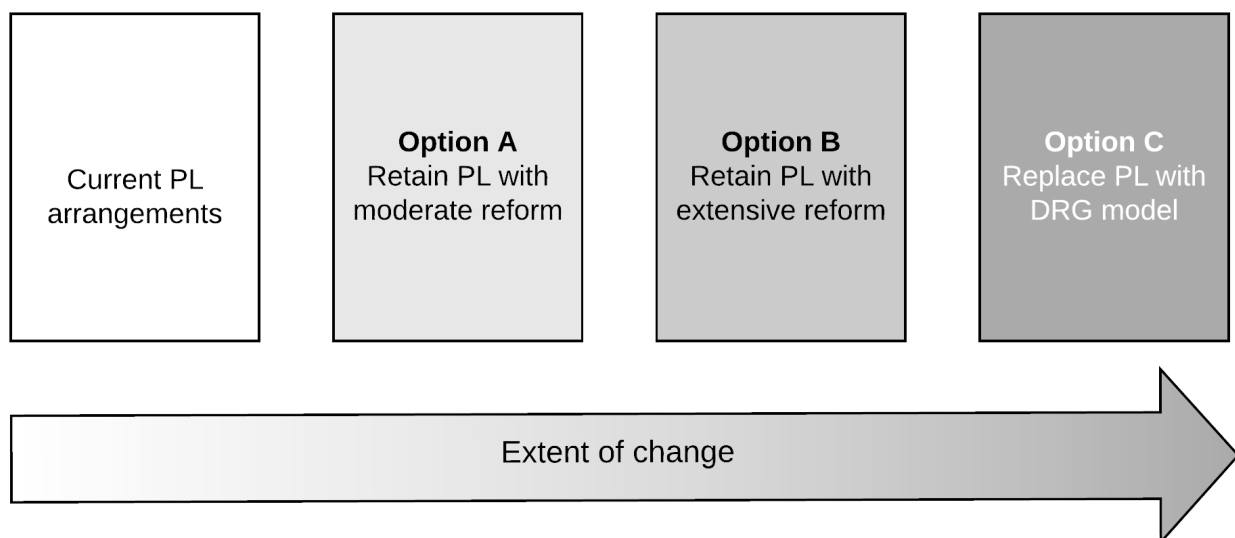
systems that reward the provision of high-quality care and innovation. The proposed options seek to achieve this in two ways:

- i. By embedding HTA principles within the prostheses assessment pathways, thereby providing a transparent mechanism for linking cost and effectiveness, and the determination of higher benefits for prostheses with superior clinical effectiveness, and
- ii. By moving away from prostheses benefits defined on the basis of individual device components (the current PL arrangements), to prostheses benefits defined on the basis of the 'package of hardware' required to perform a procedure.

CHARACTERISTICS OF THE OPTIONS

Different options for a revised framework for setting and reviewing benefits for medical devices were discussed by the BSRIWG and three options developed by the University of Sydney are presented here. The suggested options reflect a continuum from **moderate reform of current PL arrangements** (Option A), through **extensive reform of current PL arrangements** (Option B), to a **transition to a DRG model** (Option C). The key characteristics of each option are presented in Table 2. In addition, because there was not consensus on the need for reform of the current framework for setting and reviewing PL benefits³⁷, the characteristics of the options are compared with those of the current PL arrangements. Thus, the full continuum that is presented runs from the current 'fee per device component' arrangement, to a fee per whole device system' arrangement (Option A), a 'fee per procedure' arrangement (Option B), and a 'fee per episode of care' arrangement (Option C; see Figure 2).

Figure 2 Continuum of options from no change (current PL arrangements, on the left) to maximum change (replacement of the PL with a DRG model, on the right)



³⁷ The MTAA consistently presented the view that the current issues with the PL system can be addressed solely with process and administrative changes within the Department of Health.

Following a review of their discussions, the BSRIWG acknowledged that any response to the identified issues with the PL requires consideration of multiple inter-connected domains, beyond a 'simple' review of different pricing mechanisms for setting and reviewing benefits. Consequently, for each proposed option the following characteristics are considered:

- Criteria for listing on the PL
- Grouping scheme
- What is covered by individual PL benefits
- Size of the PL
- Number of PL applications per year
- Relationship between TGA approval and PL approval
- Relationship of the PL entry to the MBS
- Approach to setting prostheses benefits
- Role of the Commonwealth in assessing prostheses applications
- Role of government committees and sub-committees in setting prostheses benefits
- Approach to reviewing prostheses benefits
- Role of the Commonwealth in reviewing prostheses applications
- Role of government committees and sub-committees in reviewing prostheses benefits
- The administrative structure to support the prostheses arrangements.

Points to note

Whilst the list of characteristics above is comprehensive the BSRIWG acknowledge that the considerations are still at a fairly high level. Consequently, the options are proposed on the understanding that further work will be required to articulate the specific details of the selected option. It is anticipated that this would occur during the Planning for Implementation stage shown in Figure 1.

The options presented here relate to prostheses currently covered by Parts A and C of the PL. The approach to setting benefits for items on Part B of the PL is currently undergoing review but it is anticipated that it will also be based on fit-for-purpose HTA. The most appropriate 'listing' mechanism for human tissue products is also being reviewed, and it may (or may not) require retention of a separate list for human tissue products if Option 3 is adopted.

The members of the BSRIWG expressed different preferences for the three options. Whilst all members of the BSRIWG supported individual elements of each option, no consensus was reached about a preferred option. The BSRIWG recommend that following publication of this report there be further public consultation and that there be detailed and transparent examination of any preferred model (noting that a hybrid model might emerge during the broader consultation phase).

IMPLICATIONS OF EACH OPTION

The implications that would need to be considered for the selected option prior to implementation are shown in Table 3. These implications are framed in terms of:

- The resources needed within the Department and/or IHPA to administer the arrangements
- How the costs to administer the arrangement might be covered
- How innovation would be recognised

- Access to new health technologies
- Steps required for transition to the new arrangements

Option A – Retain the PL with moderate reform

Under this option the PL would be retained with its current purpose: to provide privately insured Australian patients with access to beneficial and cost-effective medical devices used in a medical procedure, as part of an episode of hospital or hospital-substitute care, with no patient out-of-pocket expenses for listed devices.

It is proposed that the scope of items eligible for Part A of the PL would be expanded to include implanted and non-implanted medical devices with a therapeutic intention. The number of items listed on Part A would be reduced with the removal of items that can reasonably be viewed as ‘consumables’ – namely low-unit cost/high-volume products with a non-specific use (e.g. items such as sutures, staples, and wound glue that can be used for more than one type of procedure). The structure of the PL would otherwise remain as it is, but the number of benefits listed on the PL would also be reduced as benefits would be assigned to a whole device or device system, rather than to individual device components.

Under this option the reforms to the assessment pathways proposed by the QIGIWG would be adopted, resulting in the implementation of a three-tiered approach (i.e. an Abbreviated pathway, a Focused HTA pathway, and a Full HTA pathway) to the assessment of PL applications. It is anticipated that the majority of applications would be assessed via the abbreviated pathway, and fit-for-purpose HTA methods would be used for a proportion of applications assessed via the focused HTA pathway.

The CAGs would continue to provide expert clinical input (predominantly for the focused and full HTA pathways), and the assessment of applications requiring HTA would become the responsibility of MSAC which is constituted to provide advice to the Minister on the comparative safety, effectiveness and cost-effectiveness of medical devices and services. PLAC would continue as a representative committee of private sector stakeholders advising the Government on non-HTA matters.

The setting of prostheses benefits would be undertaken according to HTA principles, with reference to existing benefits for listed items. The approach to setting PL benefits would be the same for Parts A and C (noting that some non-implantable items currently on Part C may become eligible for Part A, but Part C would probably need to be retained for exceptional circumstances).

The processes for administering the PL would continue to be undertaken by the Department. The resources to administer the arrangements would continue to be funded through cost-recovery. HTA methods would be used for reviewing prostheses benefits on a regular basis. It is proposed that a timetable and process for implementing the outcomes of such reviews would be agreed by PLAC.

If the current size and structure of the PL and the number of PL applications is maintained near current levels the Department anticipates that a substantial increase in their resourcing would be required to implement the three tiers of PL assessment pathways and to undertake benefit reviews.

Option B – Retain the PL with extensive reform

Under this option the PL would be retained with its current purpose: to provide privately insured Australian patients with access to beneficial and cost-effective medical devices used in a medical procedure, as part of an episode of hospital or hospital-substitute care, with no patient out-of-pocket expenses for listed devices.

As for Option A it is proposed that the scope of items eligible for Part A of the PL would be expanded to include implanted and non-implanted medical devices with a therapeutic intention, and items viewed as 'consumables' would be removed.

The PL would be re-structured based on therapeutic procedures rather than product characteristics (e.g. 'total knee arthroplasty' or 'partial knee arthroplasty' rather than 'whole knee joint' or 'medial/lateral knee part or kneecap'). Consideration could be given to aligning these 'therapeutic groups' with the recently defined clinical categories utilised in the PHI Hospital Treatment Product Tiers (Private Health Insurance Reforms {Amendments} Rules 2018).

Organising the items by therapeutic purpose would also allow direct linkage to the appropriate MBS items, which would facilitate monitoring of utilisation for review purposes. PL benefits would be paid for the collection of medical devices and device components used during a single procedure on an individual patient, rather than for individual devices or device components (e.g. all of the orthopaedic devices and instruments required to repair a femur, or an implanted cardiac device with all of its associated leads, battery etc).

As for Option A the reforms to the assessment pathways proposed by the QIGIWG would be adopted, resulting in the implementation of a three-tiered approach (i.e. an Abbreviated pathway, a Focused HTA pathway, and a Full HTA pathway) to the assessment of PL applications. It is anticipated that the time to market for products that qualify for the abbreviated pathway would be greatly expedited under Option B - once the TGA approves the specific uses of a device it could be immediately added to the corresponding use categories on the re-structured PL.

As for Option A, the CAGs would continue to provide expert clinical input (predominantly for the focused and full HTA pathways), and the assessment of applications requiring HTA would become the responsibility of MSAC. PLAC would continue as a representative committee of private sector stakeholders advising the Government on non-HTA matters.

The setting of prostheses benefits would be undertaken according to HTA principles, with reference to existing benefits for listed items. Benefits could be set based on the *average* 'basket' of devices used for similar types of patients undergoing the same procedure³⁸ but the exact pricing mechanism would be explored during the Implementation planning stage. The approach to setting PL benefits would be the same for Parts A and C (noting that some non-implantable items currently on Part C may become eligible for Part A, but Part C would probably need to be retained for exceptional circumstances).

The processes for administering the PL would continue to be undertaken by the Department. It is proposed that the resources to administer the arrangements would continue to be funded through cost-recovery. HTA methods would be used for reviewing prostheses benefits on a regular basis. It is proposed that a timetable and process for implementing the outcomes of such reviews would be agreed by PLAC.

Whilst Option B would reduce the size and complexity of the PL, the Department anticipates that the increased resourcing required to administer the PL would still be substantial: similar to Option A, new Departmental functions would include the management of the abbreviated pathway, regular review of pricing, regular post market review of clinical effectiveness and a new compliance function.

As for Option A, the additional resources required to manage this proposed reform would need to be funded through cost recovery.

³⁸ This is not dissimilar to what happens for pharmaceuticals when average per patient dosages are calculated, taking account of varying factors such as patient weight, patient body surface area, and wastage due to vial size

Option C – Replace the PL with a DRG model

Under this option the PL would largely be replaced by a DRG grouping model (noting that some aspects of the PL might be retained, such as a list for human tissue products and/or a list for a high-unit cost, novel technologies). It is envisaged that the new model would be administered by the Independent Hospital Pricing Authority (IHPA).

The AR-DRG model is the payment system already employed in public hospitals. It is an admitted patient classification system which provides a clinically meaningful way of relating the number and type of patients treated in a hospital (known as hospital case-mix) to the resources required by the hospital to deliver that care. Each AR-DRG represents a class of patients with similar clinical conditions requiring similar hospital services. It is proposed that a parallel 'private sector DRG model' be established as Option C, which at the outset would apply only to the prostheses component of the episode of care with benefits to be paid by insurers set for that component. Although cost components within corresponding DRGs would not necessarily be equivalent between the public and private sectors, it is anticipated that the definition of the private sector DRGs would be largely the same as current DRGs, but with additional segmenting where required (e.g. for ocular surgery).

As the PL would largely be replaced, theoretically there would be no limit on the types of prostheses that could be allowable within a single private DRG, as long as the treating doctor deemed them clinically appropriate. The operation of AR-DRGs in the private sector does not currently specify any relationship to the MBS. However, mapping of MBS items to AR-DRGs may be useful for monitoring costs for related procedures and the overall requirement that funding for use of TGA approved prostheses link to MBS funded services would be retained.

It is proposed that the 'prostheses component' of the private DRG payment would initially be set based on the total benefits for the corresponding 'package' of devices currently listed on the PL. IHPA is already able to access these data. Over time there would be no need for the abbreviated prostheses assessment pathway as products approved by the TGA could be automatically included within the appropriate DRG (i.e. time to market after TGA approval would be immediate). However, it is anticipated that there would be an ongoing need for HTA to determine the cost-effective benefit for innovative (especially high-unit cost) technologies.

To counter concerns about the DRG model, there may be a need to establish a time limited list of innovative high unit cost devices with mandated benefits to ensure that consumers have access to these in an immature market. It is proposed that any HTA that is required to supplement the DRG model would be overseen by MSAC, and the Department would manage this. However, over time, the market would establish a price and the device would move into a new or existing DRG.

It is proposed that the processes for administering the private DRG model would be undertaken by IHPA. A key part of the planning for implementation of this option would be confirming the resourcing required for IHPA to take on this role. It is proposed that processes for undertaking any supplementary HTA would continue to be undertaken by the Department of Health (although responsibility for this would shift to the MSAC section once there is no further need for the Prostheses Section).

In general, there would be no need for a formal prostheses review mechanism as price adjustments within the private DRGs would occur as a consequence of competition (as it does for AR-DRGs). That said, there may be a need to establish a review mechanism for products that are included in a private DRG on the basis of immature evidence where the subsequent emergence of new evidence might support an increase or decrease in the cost-effective DRG benefit for the device. IHPA has calculated

that a transition from the current PL arrangements to a private DRG model has the potential to save the Australian health system \$1billion per year³⁹.

³⁹ Figure cited by IHPA representative during BSRIWG discussions

Table 2 Summary of the key characteristics of each of the proposed options compared with current PL arrangements

	Current PL arrangements	Option A Retain PL with moderate reform	Option B Retain PL with extensive reform	Option C Replace PL with a DRG model
Criteria for PL listing	<ul style="list-style-type: none"> - For delivery of hospital or hospital-substitute care - TGA approved with at least one relevant MBS item - Product type: <ul style="list-style-type: none"> - Implanted only (Part A) - Human Tissue products (Part B) - Selected other devices (Part C) 	<ul style="list-style-type: none"> - For delivery of hospital or hospital-substitute care - TGA approved with at least one relevant MBS item - Product type: <ul style="list-style-type: none"> - Implanted & non-implanted high cost specific purpose used to remedy disease or dysfunction (Part A) - Human Tissue products (Part B) - Selected other devices (Part C) 	<ul style="list-style-type: none"> - For delivery of hospital or hospital-substitute care - TGA approved with at least one relevant MBS item - Product type: <ul style="list-style-type: none"> - Implanted & non-implanted specific purpose used to remedy disease or dysfunction (Part A) - Human Tissue products (Part B) - Selected other devices (Part C) 	<ul style="list-style-type: none"> - this Option transitions the focus of funding from the individual prosthesis to the procedure being undertaken. Prostheses component of DRG will be similar to Option A and B. - Link to TGA approval and MBS funded service maintained
Grouping Scheme	<ul style="list-style-type: none"> - Based on Product groups (ie, individual devices and device components, organised on the basis of product characteristics with sub-groups and suffixes.) - Includes 'consumables' (i.e. low-cost, high-volume products with a non-specific use) 	<ul style="list-style-type: none"> - Based on Product groups (ie, individual devices, organised on the basis of product characteristics with benefits paid for whole devices or product systems rather than for device components) - Would exclude 'consumables' (i.e. low-cost/high-volume products with a non-specific use) 	<ul style="list-style-type: none"> - Based on Therapeutic groups (ie, the collection of devices and device components required for a single episode of care with a specific therapeutic purpose) - Could include 'consumables' (i.e., low-cost, high-volume products with a non-specific use) 	<ul style="list-style-type: none"> - The preferred 'grouping scheme' would be the current version of the Australian Refined Diagnosis Related Groups (AR-DRGs).
Nature of a PL benefit	<ul style="list-style-type: none"> - Individual devices or device components attract individual PL benefits. 	<ul style="list-style-type: none"> - Whole devices or device systems would attract a single PL benefit. 	<ul style="list-style-type: none"> - Items would be listed by therapeutic procedure. - The basket of devices and device components used to deliver a single procedure would attract a single lumped PL benefit. - A Therapeutic group premium would be available for device systems that can demonstrate 	<ul style="list-style-type: none"> - As is currently the case with the private sector National Hospital Cost Data Collection (NHCCDC), prostheses costs are goods and services used in the provision of services to implant prostheses, human tissue item and other medical devices that are: <ul style="list-style-type: none"> - specified on the PL; or

	Current PL arrangements	Option A Retain PL with moderate reform	Option B Retain PL with extensive reform	Option C Replace PL with a DRG model
			superior cost-effectiveness compared with existing devices in a therapeutic group.	<ul style="list-style-type: none"> - assessed as being comparable in function to devices on the PL. - Over the transition period, the link to the PL would not be required as any and all expenses would be grouped under the broad category of 'prostheses'.
Size of the PL	<ul style="list-style-type: none"> - More than 11,600 PL billing codes with tens of thousands of items. - More than 1700 unique groupings 	<ul style="list-style-type: none"> - Thousands of individual devices and device components would continue to be listed, but <11,600 - Hundreds of unique groupings expected, but <1,000 	<ul style="list-style-type: none"> - Thousands of individual devices would continue to be listed, but fewer than with Option A. - Hundreds of unique groupings expected, but fewer than Option A 	<ul style="list-style-type: none"> - Initially the existing PL would be utilised but ultimately the role of the device-specific PL would be subsumed into the procedure-specific DRG approach. - The number of DRGs used in the private sector is expected to be lower than the ~800 DRGs used in the public sector. Approximately 400 of current public sector DRGs have a device cost component.
Number of PL applications per year	- 1,500 to 2,000	- Expected to be <2,000	- Expected to be less than Option A	Not applicable
Relationship between TGA approval and PL approval	- All sponsors of a TGA-approved device must apply for the device to be added to the PL	- All sponsors of a TGA-approved device must apply for the device to be added to the PL	<ul style="list-style-type: none"> - Most devices with a TGA Risk classification Class IIb or lower will be added to the PL as soon as TGA approval is granted and the proposed PL Therapeutic group has been accepted by the Department. - Sponsors of a device with a TGA Risk classification of Class III or AIMD would still be required to apply for the device to be added to the PL. 	- Subject to TGA approval a device could be utilised immediately and the costs associated with it recorded against the relevant private DRG.

	Current PL arrangements	Option A Retain PL with moderate reform	Option B Retain PL with extensive reform	Option C Replace PL with a DRG model
Relationship of PL entry to the MBS	- MBS item(s) required for every PL listing but MBS items not required to be included to each PL entry.	- MBS item(s) required for PL listing and all relevant MBS items would be included in a PL entry for each device.	- MBS item(s) would be included for each therapeutic group entry on the PL.	- There would be no requirement for prostheses to be explicitly linked to MBS items but overall requirement maintained.
Approach to setting prostheses benefits	<ul style="list-style-type: none"> - Overall approach is not risk-based. - Initial setting of PL benefits not universally based on HTA - predominantly on clinical assessment of device characteristics, with limited consideration of incremental cost-effectiveness. - Partially fit-for-purpose PL assessment pathways (adopted only in last 12 months): <ul style="list-style-type: none"> - Business as usual pathway no HTA, the majority of applications for new listings are considered by CAGs and PLAC regardless of the TGA risk classification for each device. - Focussed HTA pathway for a selection of applications for new listings that are seeking a higher benefit or seeking an equivalent benefit on the basis of a claim of superiority. - Full HTA Pathway only for devices where there is no corresponding item on the MBS, regardless of the TGA risk classification of each device. 	<ul style="list-style-type: none"> - Overall approach is risk-based. - Initial setting of PL benefits for new items is based on HTA principles, with higher benefits for items that can demonstrate superior clinical and/or economic outcomes (ie, are cost-effective relative to a comparator). - Fully fit-for-purpose HTA pathways: <ul style="list-style-type: none"> - Abbreviated pathway no HTA, applications for most applications seeking new listings for Class IIb or lower devices that are not seeking a higher benefit. - Focussed HTA pathway for a selection of applications for new listings that are seeking a higher benefit or seeking an equivalent benefit on the basis of a claim of superiority. - Full HTA Pathway for innovative (new class) devices or where there is no corresponding item on the MBS. 	<ul style="list-style-type: none"> - Overall approach is risk-based. - Initial setting of PL benefits for new items is based on HTA principles, with higher benefits for items that can demonstrate superior clinical and/or economic outcomes (ie, are cost-effective relative to a comparator). - Streamlined HTA pathways for medical devices and medical services: <ul style="list-style-type: none"> - Abbreviated pathway for devices that are not seeking a therapeutic group premium. Assessment would be limited to checking the proposed therapeutic group based on the nominated MBS item(s) - MSAC pathway for a selection of applications for new listings that are seeking a higher benefit or seeking an equivalent benefit on the basis of a claim of superiority; and for innovative (new class) devices or for devices where there is no corresponding item on the MBS. 	<ul style="list-style-type: none"> - Generally not applicable - Initially the existing PL would be utilised but ultimately role of the device specific PL will be subsumed into the procedure specific DRG approach. - MSAC pathway may still be required to set benefits for high-cost and/or higher risk products, to supplement the work of IHPA.

	Current PL arrangements	Option A Retain PL with moderate reform	Option B Retain PL with extensive reform	Option C Replace PL with a DRG model
Role of the Commonwealth in assessing prostheses applications	- Nil	<ul style="list-style-type: none"> - The Prostheses Section of the TAAD would be responsible for undertaking all assessments submitted via the Abbreviated pathway. - The Medical Services and Technology Section of the TAAD would be responsible for undertaking or co-ordinating all assessments via the Focussed or Full HTA Pathways. 	<ul style="list-style-type: none"> - The Prostheses Section of the TAAD would be responsible for undertaking all assessments submitted via the Direct to PL pathway - The Medical Services and Technology Section of the TAAD would be responsible for undertaking or co-ordinating all other assessments. 	<ul style="list-style-type: none"> - IHPA would not undertake assessments of individual prostheses. - The Medical Services and Technology Section of the TAAD would be responsible for undertaking or co-ordinating a limited number of assessments, generally on referral from IHPA.
Role of government committees and sub-committees in setting prostheses benefits	<ul style="list-style-type: none"> - CAGs provide advice to PLAC on the similarities and differences of devices for the majority of applications for new listings. - PLAC provides advice to the Delegate on the PL benefit for each device, informed by an economic evaluation if the application has been assessed via the Focussed or Full HTA pathway. - MSAC provides advice to the Minister and to PLAC on the MBS benefit for the associated medical service(s) and the descriptor for the MBS item, and may also provide advice on the PL benefit at which the total procedure (including both the device and the medical service) is unlikely to be cost-effective. 	<ul style="list-style-type: none"> - CAGs would provide advice to MSAC and the Department on the similarities and differences of devices for the majority of applications for new listings. - MSAC provides advice to the Minister and to PLAC on the MBS benefit for the associated medical service(s) and the descriptor for the MBS item, and may also provide advice on the PL benefit at which the total procedure (including both the device and the medical service) is unlikely to be cost-effective. 	<ul style="list-style-type: none"> - CAGs would provide advice to MSAC and the Department on the similarities and differences of devices, as required, but always for novel devices. - PLAC could be involved in the initial benchmarking of benefits for the PL therapeutic groups - MSAC would provide advice to the Delegate on the PL benefit and to the Minister on the MBS benefit for the associated medical service(s) and the descriptor for the MBS item. 	<ul style="list-style-type: none"> - Under a fully implemented activity-based funding system there would be no role for CAGs or PLAC. - MSAC would provide advice to IHPA for new to market, high cost technology.
Approach to reviewing prostheses benefits	- Limited monitoring of individual PL item usage after listing due to limited	- More extensive monitoring of individual PL item usage and MBS item utilisation after listing	- More extensive monitoring of individual PL item usage and MBS item utilisation after listing	- IHPA would review prostheses benefits using usual price disclosure process currently operating in public sector.

	Current PL arrangements	Option A Retain PL with moderate reform	Option B Retain PL with extensive reform	Option C Replace PL with a DRG model
	<p>resourcing within TAAD and incomplete data.</p> <ul style="list-style-type: none"> - Overall approach is for infrequent reviews. - Limited adjustment of PL benefits for individual items after listing with no agreed method for increasing or decreasing benefits. 	<ul style="list-style-type: none"> - Overall approach would be for regularly occurring reviews using HTA methods, and reference pricing according to an agreed timetable. - More frequent adjustment of PL benefits for individual items after listing according to a method based on HTA principles. 	<ul style="list-style-type: none"> - Overall approach would be for regularly occurring reviews using HTA methods and price setting mechanisms including tendering and reference pricing, according to an agreed timetable. - More frequent adjustment of PL benefits for individual items after listing according to a method based on HTA principles. 	<p>Initial DRG benefit setting and review could use reference pricing to public sector.</p> <ul style="list-style-type: none"> - Might be occasions where post-market review of prostheses benefits is warranted and this could be undertaken by MSAC.
Role of the Commonwealth in reviewing prostheses benefits	-	<ul style="list-style-type: none"> - Prostheses Section of the TAAD would suggest the approach to each review (governance, process, and methods) and co-ordinate the review (undertaken internally and/or externally) once approved by PLAC. 	<ul style="list-style-type: none"> - Prostheses Section of the TAAD would suggest the approach to each review (governance, process, and methods) and co-ordinate the review (undertaken internally and/or externally) once approved by PLAC. 	<ul style="list-style-type: none"> - IHPA would undertake with involvement of MSAC on request
Role of government committees and sub-committees in reviewing prostheses benefits	<ul style="list-style-type: none"> - PLAC prioritises categories or groups to be reviewed. - Prostheses Section of the TAAD suggests approach to each review (governance, process, and methods) and co-ordinates the review (undertaken internally and/or externally). - PLAC considers findings from review and provides advice to the Minister regarding changes to the PL in response to the review. 	<ul style="list-style-type: none"> - PLAC would prioritise categories or groups to be reviewed and agrees timetable. - PLAC would consider findings from each review and provide advice to the Minister regarding changes to the PL in response to the review. 	<ul style="list-style-type: none"> - MSAC would regularly review Predicted vs Actual analyses of medical devices and related medical services and provide advice to the Department and the Minister, as appropriate. - PLAC and/or the CAGs would be invited to provide advice to MSAC regarding the interpretation of the Predicted vs Actual analyses as they relate to medical devices. 	<ul style="list-style-type: none"> - MSAC could advise IHPA on any changes to the cost-effective benefit for high-cost devices as new evidence is emerges.
Administrative structure to support prostheses arrangements	<ul style="list-style-type: none"> - The Prostheses Section of the TAAD is responsible for processing all new applications for new listings and amendments. 	<ul style="list-style-type: none"> - The Prostheses Section of the TAAD would be responsible for processing all new applications for new listings and amendments. 	<ul style="list-style-type: none"> - The Prostheses Section of the TAAD would be responsible for processing all new applications for new listings and amendments. 	<ul style="list-style-type: none"> - IHPA would have primary responsibility for administering the private DRG model.

	Current PL arrangements	Option A Retain PL with moderate reform	Option B Retain PL with extensive reform	Option C Replace PL with a DRG model
	<ul style="list-style-type: none"> - The Prostheses Section of the TAAD is responsible for monitoring and maintaining the PLMS. - The Prostheses Section of the TAAD is responsible for providing secretariat support to PLAC (which meets 4 times per year), the 8 CAGs (which each meet 3 times per year) and the Panel (which meets as required). - The Prostheses Section of the TAAD is responsible for triaging applications for new listings, and co-ordinating the engagement of an external HTA contractor via the Focussed HTA Pathway, when required. - The Prostheses Section of the TAAD collates advice from the CAGS and PLAC for the Delegate. - There is no resourcing for regular monitoring of PL utilisation 	<ul style="list-style-type: none"> - The HPP system (the replacement for PLMS) will be managed centrally. - The Prostheses Section of the TAAD would be responsible for providing secretariat support to PLAC (which meets 4 times per year), the 8 CAGs (which each meet 3 times per year) and the Panel (which meets as required). - The Prostheses Section of the TAAD is responsible for triaging applications for new listings, undertaking assessments submitted for the Abbreviated pathway, and co-ordinating the engagement of an external HTA contractor via the Focussed HTA Pathway, when required. - The Prostheses Section of the TAAD would collate its internal advice, together with advice from the CAGS and PLAC for the Delegate. 	<ul style="list-style-type: none"> - The HPP system (the replacement for PLMS) will be managed centrally. - The Medical Services and Technology Section of the TAAD would be responsible for undertaking regular Predicted vs Actual analyses of related medical devices and services and tabling these for MSAC consideration. 	<p>The Medical Services and Technology Section of the TAAD would be responsible for providing assessment of a limited number of applications to IHPA (these are expected to be applications for new MBS services using devices that MSAC would normally assess, so would not represent additional work for the MSAC section).</p>

Table 3 Implications of each Option that would need to be considered in more detail prior to implementation

	Current PL arrangements	Option A: Moderate reform of the PL	Option B: Extensive reform of the PL	Option C: Private hospital DRG model
Resources needed within the Department to administer the arrangements	- Maintenance of current levels of resourcing within the Department	- Estimated up to 5x more resources within the Department to administer the PL (depending on the size of the PL), undertake internal assessments for the Abbreviated pathway, commission assessments via the Focused HTA pathway, and to undertake regular monitoring and reviews of the PL.	- Estimated 4-5x more resources within the Department to administer the PL, undertake internal assessments for the Abbreviated pathway and commission external HTA reports, and to undertake regular monitoring and reviews of the PL.	- No more than current levels of resourcing within the Department would be required. Additional resources for IHPA
How the costs to administer the arrangements would be covered	- The Department currently administers the PL arrangements on behalf of three industry stakeholders (sponsors, PHIs, and private hospitals), but cost recovery is only from sponsors .	- The Department currently administers the PL arrangements on behalf of three industry stakeholders (sponsors, PHIs, and private hospitals). Increased resourcing would need to be funded through cost recovery .	- The Department currently administers the PL arrangements on behalf of three industry stakeholders (sponsors, PHIs, and private hospitals). Increased funding would need to be funded through cost recovery .	- IHPA is funded by the Commonwealth
Recognition of innovation	- Without a formal framework for assessing comparative safety, effectiveness and cost-effectiveness it is not possible to determine appropriate higher PL benefits for devices that are associated with superior effectiveness. - Often not feasible to generate high-level clinical evidence when the unit of study is a device component rather than a device system. - Difficult to recognise innovation at the time of initial benefit setting or when benefits are reviewed.	- With a formal HTA framework for assessing comparative safety, effectiveness and cost-effectiveness it would be possible to determine appropriate higher PL benefits for devices that are associated with superior effectiveness. - Provides a framework for recognising innovation at the time of initial benefit setting and when benefits are reviewed.	- With a formal HTA framework for assessing comparative safety, effectiveness and cost-effectiveness it would be possible to determine appropriate higher PL benefits for devices that are associated with superior effectiveness. - Provides a framework for recognising innovation at the time of initial benefit setting and when benefits are reviewed.	- There would need to be mechanism for recognising innovation that was an adjunct to the DRG model (e.g. a separate device-specific DRG with a higher benefit for a novel device that has demonstrated cost-effectiveness).
Access to new health technologies	Time to inclusion on the PL	Time to inclusion on the PL	Time to inclusion on the PL	Time to inclusion on the PL

	<ul style="list-style-type: none"> - Typically some months from the time of PL application to inclusion on the PL when there is an existing MBS item. - Longer time-frames if a new MBS item is required. <p>Clinician choice</p> <ul style="list-style-type: none"> - Availability of sub-groups and suffixes incentivises sponsors to supply a range of products for the PL from which clinicians can choose specific products. <p>Patient choice</p> <ul style="list-style-type: none"> - Patients choose items on the PL indirectly: they choose their clinician, and their clinician chooses the item they consider to be most appropriate for the patient. 	<ul style="list-style-type: none"> - Shorter time to listing than current arrangements for applications assessed via the Abbreviated pathway - Similar time to listing as current arrangements for applications assessed via the Focused HTA pathway - Similar time to listing as current arrangements if a new MBS item is required. <p>Clinician choice</p> <ul style="list-style-type: none"> - Reduction in the number of sub-groups and suffixes may result in some sponsors withdrawing items from the PL, which would reduce the range of products available to clinicians. <p>Patient choice</p> <ul style="list-style-type: none"> - Patients will continue to choose items on the PL indirectly: they will choose their clinician, and their clinician will choose the item they consider to be most appropriate for the patient. The reduction in choice for clinicians may or may not impact on patient outcomes. 	<ul style="list-style-type: none"> - Shorter time to listing than current arrangements for applications assessed via the Abbreviated pathway - Similar time to listing as current arrangements for applications assessed via an MSAC HTA pathway. <p>Clinician choice</p> <ul style="list-style-type: none"> - Available within the policies and procedures of the private facility <p>Patient choice</p> <ul style="list-style-type: none"> - Patients will continue to choose items on the PL indirectly: they will choose their clinician, and their clinician will choose the item they consider to be most appropriate for the patient. 	<ul style="list-style-type: none"> - Under full implementation of DRGs the 'time to inclusion' for 'like prostheses' is effectively zero months as the path to billing is achieved immediately upon TGA approval. <p>Clinician choice</p> <ul style="list-style-type: none"> - Available within the policies and procedures of the private facility. <p>Patient choice</p> <ul style="list-style-type: none"> - As with other options patients choose their prosthesis indirectly: they choose their clinician, and their clinician chooses the prosthesis they consider to be most appropriate for the patient.
Steps required for transition	- N/A	<ul style="list-style-type: none"> - Formal definition in legislation of the purpose and scope of the PL. - Audit of separate listings for device components that would need to be collapsed into 'device systems or kits.' - Agreement on the methods to be used to set benefits for the collapsed 	<ul style="list-style-type: none"> - Formal definition in legislation of the purpose and scope of the PL. - Audit and analysis of PL items and associated procedure items to define new therapeutic groups and establish therapeutic group benefits. - Development of compliance function 	<ul style="list-style-type: none"> - Will require a significant transition period under the leadership of IHPA. - IHPA's current primary function is to calculate and deliver an annual National Efficient Price (NEP). The NEP is a major determinant of the level of Australian Government funding for public hospital services and provides a price

		<p>for the newly defined device systems/kits.</p> <ul style="list-style-type: none"> - Agreement on the methods used to set benefits - Development of compliance function - Implementation could be staged with stage one the initial consolidation of the PL and benefit setting. 	<ul style="list-style-type: none"> - Implementation could be staged with stage one the initial consolidation of the PL and benefit setting. 	<p>signal or benchmark for the efficient cost of providing public hospital services.</p> <ul style="list-style-type: none"> - Under this option this 'primary function' would broaden to incorporate the private sector although at this stage it will be confined to the prostheses component of the DRG. - One transition path would be the operation of this Option in parallel with status quo as a 'shadow pricing' exercise. Subsequently an agreed path to transition could be negotiated over a short period (1/2/3 years). - The advantage of the 'shadow pricing' period would be the ability to confirm areas where the option does not work ideally and work to address.
--	--	---	--	---

APPENDIX 1 MEMBERSHIP AND TERMS OF REFERENCE OF THE BSRIWG

The full Terms of Reference and Operating Guidelines for the BSRIWG are available on the Department of Health website⁴⁰. In summary, the role of the BSRIWG is to develop and provide a report to the Prostheses Reform Governance Group that sets out options for a revised framework for setting and reviewing benefits for devices on the PL. It was noted that stakeholders would be consulted during the development of the report.

The specific function of the BSRIWG was to review the current framework for benefit setting and benefit review for medical devices under the PL to ensure the future PL framework:

1. is tailored to medical technology,
2. has a structure and associated processes that are simple, administratively efficient, pragmatic and sustainable,
3. is not duplicative of other HTA processes,
4. is informed by robust and relevant evidence, including, for market considerations, credible data,
5. encourages competition,
6. is built on transparent processes with appropriate protections around commercial-in-confidence data,
7. provides flexibility to differentiate between product groups/sub-groups,
8. is compatible with the incorporation of new and cost-effective technologies, and
9. recognises improvements in value.

In developing options for a revised framework for setting and reviewing benefits the BSRIWG was to give regard to:

- the strengths and weaknesses of the current benefit setting and review framework;
- practicable approaches for demonstrating the cost-benefit of devices;
- the circumstances under which HTA might apply;
- how 'value' should be defined in the context of medical devices;
- how the following parameters should be assessed – (i) validated patient reported outcome measures, (ii) substantial equivalence for the purposes of benefit setting and review, (iii) superior efficacy or performance over a comparator at the time of benefit setting and also at the time of benefit review.

40

[https://www1.health.gov.au/internet/main/publishing.nsf/Content/9F57F7ABB269BCCDCA25826C007BFD2B/\\$File/Revised%20Benefit%20Setting%20and%20Review%20Framework%20IWG%20-%20Terms%20of%20Reference.pdf](https://www1.health.gov.au/internet/main/publishing.nsf/Content/9F57F7ABB269BCCDCA25826C007BFD2B/$File/Revised%20Benefit%20Setting%20and%20Review%20Framework%20IWG%20-%20Terms%20of%20Reference.pdf)

- how the framework fosters and encourages innovation;
- criteria and processes for listing medical technologies that do not fit the definition of Part A of the PL;
- the transparency requirements in relation to the assessment of PL applications;
- mechanisms for reviewing benefits of devices/technologies on the PL;
- an appropriate review timetable;
- transparent review processes for Sponsors;
- refining the grouping schemes under the PL to support a more efficient listing process;
- the role of real-world data in benefit setting and benefit review; and

The Terms of Reference also state that options developed by the BSRIWG should:

- improve the transparency of medical device benefit setting on the PL
- support the building of stakeholder and consumer confidence in PL benefits
- support fair reimbursement to sponsors and suppliers for their products
- support fair reimbursement to hospitals for the costs they incur in providing medical devices to patients
- be manageable and sustainable in terms of costs to operate – and that the costs will not be disproportionately burdensome for stakeholders, and
- include a risk assessment and advise on ease of implementation and potential transition arrangements.

The membership of the BSRIWG is shown in the table below (in alphabetical order by surname, with the Chair listed first). The table also shows the duration of appointment for each member, and the organisation or entity represented by them. Past and present members are included in the table. Original members are indicated with an Asterix (*). Members were endorsed by the Prostheses Reform Governance Group, and were appointed by the Assistant Secretary, Office of Health Technology Assessment Branch, Department of Health as members of a departmental committee for financial management purposes.

Member	Organisation/entity represented	Type of member	Appointment duration
Emeritus Professor Terry Campbell AM *	Chair of PLAC (Chair, BSRIWG)	<i>Government</i>	Apr 2018 – current
Mr Maurice Ben-Mayor	Stryker Australia	<i>Manufacturers</i>	May 2018 – Feb 2019
Ms Emma Bognar *	Australian Private Hospitals Association	<i>Private hospitals</i>	Apr 2018 – current
Mr Ian Burgess	Medical Technology Association of Australia	<i>Manufacturers</i>	Apr 2018 – current
Mr Paul Dale *	Medical Technology Association of Australia	<i>Manufacturers</i>	Feb 2019 – current

Dr Rachel David	Private Healthcare Australia	<i>Private insurers</i>	Apr 2018 – Apr 2018
Mr James Downie	Independent Hospital Pricing Authority	<i>Government</i>	Apr 2018 – current
Ms Sarah Griffin *	Medtechnique	<i>Manufacturers</i>	Apr 2018 – current
Dr Megan Keaney *	Department of Health	<i>Government</i>	Apr 2018 – current
Ms Andrea Kunca	Medical Technology Association of Australia	<i>Manufacturers</i>	Apr 2018 – Nov 2018
Ms Gabrielle Moreland *	Day Hospitals Australia	<i>Private hospitals</i>	Apr 2018 – current
Mr Craig Moy *	Private Healthcare Australia	<i>Private insurers</i>	Oct 2018 – current
Mr Matt Muscio *	LifeHealthcare	<i>Manufacturers</i>	Apr 2019 – current
Mr Ian Noble *	Noble Consulting	<i>Manufacturers</i>	Apr 2018 – current
Mr George Papadopoulos *	AusBiotech	<i>Manufacturers</i>	Apr 2018 – current
Ms Cathy Ryan	Catholic Health Australia	<i>Private hospitals</i>	Apr 2018 – current
Ms Georgina Sanderson	Cochlear Limited	<i>Manufacturers</i>	Apr 2018 – Dec 2018
Ms Andrea Selleck *	Australian Regional Health Group	<i>Private insurers</i>	Apr 2018 – current
Mr Michael Simmonds	Boston Scientific	<i>Manufacturers</i>	Mar 2018 – Feb 2019
Mr Paul Suebwongpat *	Cochlear Limited	<i>Manufacturers</i>	Dec 2018 – current
Dr Jui Tham *	Members Health Fund Alliance	<i>Private insurers</i>	Apr 2018 – current
Dr Janney Wale *	Consumers Health Forum	<i>Consumers</i>	Apr 2018 – current
Mr Andrew Wiltshire *	Medtronic	<i>Manufacturers</i>	Feb 2019 – current