

Industry Working Group on Private Health Insurance Prostheses Reform

Final Report

Overview and Further Considerations

The Industry Working Group on Private Health Insurance Prostheses Reform (IWG) was established to examine opportunities for reform of the arrangements governing prostheses and devices access in the private health insurance sector. The Terms of Reference required the IWG to assess the current system, including the Prostheses List Advisory Committee (PLAC) and its attendant Clinical Advisory Groups (CAGs) and Panel of Clinical Experts (PoCE), and to provide advice to the Department of Health (the Department) on:

1. Creating a more competitive basis for purchase and reimbursement of prostheses and devices, including consideration of options for new pricing mechanisms;
 2. Specific products or categories which present opportunities for immediate benefit rationalisation;
 3. Refining the scope of products currently listed on the Prostheses List (PL) without adversely impacting consumer access; and
 4. Opportunities for deregulation.
1. In respect of creating a more transparent and competitive basis for purchase and reimbursement of prostheses, the IWG agreed:
- that a PL be maintained to ensure consumers and clinicians can access a reasonable choice of clinically relevant prostheses, reimbursed by insurers, preferably without a consumer co-payment;
 - that in setting a benefit for a device, consideration should be given to appropriate costs for inclusion in the benefit, including any clinically relevant requirements of the device (e.g. in-theatre assistance, software, maintenance/monitoring and product support etc.);
 - that should Government seek medium term benefit reductions across the PL, it would be appropriate to consider legislating a price disclosure system for prostheses, encompassing both public sector and private sector medical device pricing;
 - that reference pricing, taking into account domestic and relevant international prices, be considered as a mechanism to set the PL benefit;
 - consideration should be given to establishing a mechanism to ensure service providers are reimbursed for the appropriate costs of maintaining inventory to encourage timely access to prostheses.
2. In respect of specific products which present opportunities for immediate benefit rationalisation, the IWG considered analysis of data performed by the Chair and the Department, and noted that the PL benefits in device categories of Cardiac, Intra-Ocular Lens Systems (IOLS), Hips and Knees appear to be significantly higher, in many cases, than market prices based on available domestic and international data. Should Government be inclined to make immediate benefit reductions, these categories should be considered for the initial targets taking into account relative price disparities.

3. In respect of refining the scope of products on the PL, the IWG agreed:
 - that if items are considered for removal in order to rationalise the PL, adequate time must be provided to allow new funding arrangements to be put in place;
 - that further consideration is given to amending the PL criteria to include innovative medical technologies, which are demonstrably safe, effective and cost-effective but which don't meet the current PL criteria.

4. In respect of deregulation, the IWG agreed:
 - the Government should consider opportunities for enhanced co-operation between the PLAC and the Therapeutic Goods Administration (TGA), to ensure that activities are not inappropriately duplicated;
 - that PLAC should consider developing a routine process for the assessment of devices for possible removal from the PL on clinical or cost-effectiveness grounds;
 - that consideration should be given to revising the PLAC and its advisory committee arrangements, to:
 - ensure that committee membership is based on appropriate expertise;
 - maintain an independent Chair;
 - include a greater range of members on the PLAC, specifically:
 - additional health economics expertise
 - an expert member of the Medical Services Advisory Committee (MSAC), to ensure alignment of related activities;
 - review the role of CAGs;
 - introduce the regular review of items on the PL and their PL benefits;
 - utilise existing health technology assessment (HTA) expertise as appropriate, for example the possible use of MSAC sub-committees to examine claims of clinical superiority in a cost-effectiveness framework;
 - consider the role of registries, and interact meaningfully with current registries as part of listing and delisting processes;
 - that Government should consider developing new PL Guidelines in respect of the listing process and the benefit setting process.

Summary

The IWG was established by the Department in February 2016 to examine opportunities for reform of the arrangements governing prostheses and medical devices access and pricing. The Terms of Reference for the IWG are attached (Attachment A).

Membership of the IWG was drawn from a range of relevant stakeholders, including the medical devices industry (both companies represented by the Medical Technology Association of Australia (MTAA) and independent companies), private for-profit and not-for-profit hospitals, consumers, private health insurers, the medical profession and the Department of Health. Membership of the IWG is attached (Attachment B).

Under current private health insurance regulations, “prostheses” are surgically implanted prostheses, human tissue and other medical devices for which private health insurers must pay defined benefits (Attachment C). Under the current arrangements, prostheses are assessed by PLAC to determine their comparative clinical effectiveness and the proposed private health insurance benefits. All prostheses on the Prostheses List (except for Human Tissues) are listed in groups of similar clinical effectiveness and all prostheses within a group are paid the same group benefit (or lower if the sponsor so chooses). The IWG agreed that benefit differences should only exist where a sponsor is able to provide data which is acceptable by PLAC, which demonstrates improved clinical outcomes; items which deliver the same clinical outcome should be listed at the same benefit.

The IWG considered analysis of data performed by the Chair and the Department, and noted that Prostheses List benefit levels for certain items are significantly higher than prices in the Australian hospital system and internationally. The analysis suggests that while the price-benefit differentials are not consistent across the product range, for some items the difference is substantial. These differences provide an opportunity to consider a material reduction in benefits for certain items, and therefore for reductions in private health insurance outlays.

The IWG has agreed that should the Minister for Health seek an immediate reduction in benefit outlays, then it would be appropriate for her to consider reductions in four key, high cost categories of the Prostheses List: cardiac, IOLS, hips and knees. These categories are considered appropriate for initial consideration for benefit reduction because they have large volumes and benefits paid, with relatively high levels of competition among prostheses sponsors. The IWG considers that an across-the-board reduction in prostheses benefits would be inappropriate. This is because existing price-benefit differentials are not uniform across all products and do not take into account clinically relevant differences in additional service provision.

In the longer term, price disclosure would ensure that lower prostheses prices achieved through competition are reflected in private health insurance benefits, with the potential for premiums to be lower than they would otherwise be. Under price disclosure, sponsors would

be required to provide the Department with information relating to their selling price, the cost of sales incentives and volume sold in both the private and public sectors. Price disclosure has been successful in achieving price reductions for the Pharmaceutical Benefits Scheme. The IWG agreed that a price disclosure scheme for prostheses would have some merit, and would be preferable to uniform across-the-board reductions in benefits. Differences between the prostheses and pharmaceutical system would need to be considered in developing such a price disclosure program.

The IWG discussed whether a rationalisation of the list would be an option. The IWG also discussed whether the inclusion of low-priced items on the Prostheses List creates an undue regulatory burden for sponsors and others in the supply chain. Most members of the IWG expressed the view that the inclusion of low priced items on the prostheses list did not represent a regulatory burden. The IWG was not able to reach agreement on the delisting of low-priced items.

The IWG noted that the role of PLAC is to provide advice to the Minister on listing of items based on their comparative safety and efficacy and cost-effectiveness, and agreed that this function should continue.

The IWG agreed that PLAC functions should be expanded to include a routine process of post-marketing monitoring and reviews. The IWG agreed that where this occurs it must be appropriately funded. The IWG noted that post-market reviews may lead to recommendations for the de-listing of items from the PL, and that where that occurs, any concerns regarding safety and efficacy should be referred to the TGA for consideration and further action as appropriate. The IWG noted some stakeholders held long-standing concerns regarding the lack of interaction and feedback between the TGA and PLAC; however, it was agreed that these were issues for the Review of Medicines and Medical Devices, and were not issues which could be addressed by this group.

The current regulation of the PL is a challenge for funding novel medical devices, including non-implantable devices, which do not fit the rigid definition of prostheses for the purpose of the List. This is expected to become more of an issue in the future with the rapid development of novel medical technology, including through 3D printing of individualised prostheses. The IWG agreed that the definition of prostheses for the purpose of the PL should be reviewed. However, the private health fund representatives were strongly of the view point that such a consideration must only occur in the context of a revision of the benefit setting, as set out earlier in this report.

The IWG considered at length the issues involved in reducing prostheses benefits and recommends that any potential policy changes are considered in the context of the following issues. The IWG was concerned to ensure that the potential differential impact of benefit reductions on smaller companies is considered before any reductions are applied. In addition,

the IWG noted the value of patient/surgeon choice of prostheses, and the risk that this could be reduced if products are withdrawn by sponsors from the PL as a result of the benefit reductions. The IWG discussed the need to provide pricing/benefit information to stakeholders to inform their choices. The IWG also noted the risk that out-of-pocket costs may increase, and noted that in the PBS a number of items carry a comparatively small “brand premium” which patients are required to pay. It is likely that if there is to be a prostheses “brand premium”, that premium is likely to be substantially higher than the PBS “brand premium”. The IWG noted that PL benefit reductions could impact on public sector prostheses purchasing, although it was not possible to predict what that impact would be. Finally, the IWG agreed that there is a risk that benefit reductions could lead to a reduction in access to new technology if sponsor margins are materially affected. It was agreed that any reform process must take account of the ability of all stakeholders to adjust to pricing and governance changes.

Should Government decide to progress the reforms to prostheses arrangements outlined in this report, it is recommended that Government commit to a review of the new arrangements. In relation to price disclosure, the longer lead times for implementation would not allow for a review until 2021-22.

Discussion

The IWG held four meetings during February and March 2016. Discussion centred around the four key elements of the Terms of Reference as outlined above.

Creating a more competitive basis for purchase and reimbursement of prostheses

The IWG supports the continued operation of a Prostheses List – both in terms of listing devices for reimbursement, and setting the level of benefit. In general, members were of the view that continuing to have a PL regulated by government ensures that patients and their treating practitioners can continue to access a range of clinically effective medical devices and that insurers are required to reimburse these devices preferably with no requirement for additional co-payments.

Some stakeholders, outside of the IWG members, were of the view that the PL could be fully deregulated, with contractual arrangements between insurers, hospitals and prostheses sponsors revised to accommodate the cost of prostheses as part of a clinical episode, as occurs for a wide range of other costs (for example, anaesthetic gasses and in-theatre consumables). The IWG was advised by technical adviser, Professor Graeme Samuel AC, that if deregulated, collective purchasing arrangements for prostheses could be developed through consultation with the Australian Competition and Consumer Commission (ACCC). A number of members of the IWG advised that industry would not be able to manage full deregulation of the PL in the short term, because the required systems are not in place and would take some time to develop. The IWG was of the view that immediate deregulation of the Prostheses List would not be appropriate.

The IWG recognised that there is a general lack of transparency in the current listing arrangements, particularly in respect of the relationship between the PL benefit and the market price of a device, and agreed that it would be desirable for Government to introduce more transparency into the system. In relation to the setting of benefits, the IWG agreed that consideration could be given by PLAC in assessing the cost effectiveness of listed items, to considering the full cost of providing relevant clinical services, rather than the cost of the prosthesis only. PLAC could link to existing HTA processes (such as MSAC) to undertake such cost effectiveness analyses.

The recognised lack of transparency also mitigates against a true understanding of the market for prostheses on the PL, and most likely hides significant systemic issues such as cross-subsidisation between private and public health systems, the use of 'loss leaders' to generate market share, and the use of incentives for hospitals and surgeons. This inherent opacity also means that legitimate costs which should be included in a PL benefit, cannot be reimbursed appropriately.

The IWG discussed several different approaches to improving transparency in the system. Health insurers presented a number of models of international reference pricing (IRP) for discussion by the IWG, based on work undertaken by Private Healthcare Australia and Monash University. The MTAA presented a price benchmarking approach which could be adopted, based on weighted averaging of public and private sector prices, net of rebates. The participants raised some concerns about the model, but agreed that the model is similar to price disclosure and that some form of price disclosure would be appropriate. The Department presented an overview of the Pharmaceutical Benefits Scheme (PBS) price disclosure arrangements, and noted its potential applicability to prostheses.

The IWG considered and discussed these models, and generally agreed that international pricing information was an informative input to the consideration of benefit levels. However, the use of an IRP model would have intrinsic difficulties due to the different nature of health systems in different countries. The IWG also noted that a benchmarking system was similar to price disclosure as it operates under the PBS, and that if the Government were inclined to move towards greater transparency in prostheses benefit setting, then a price disclosure model based on the PBS, but taking into account differences in the pharmaceutical and prostheses industries, should be further explored.

The IWG spent a considerable amount of time discussing the so-called "2 year evidence rule" and the "25% market share rule". It was put to the IWG that the 2 year evidence rule reduces patient access inappropriately. It was agreed that Government should consider the introduction of a managed entry scheme to provide consumers with access to products which are listed on the ARTG but do not meet the 2 year evidence rule. The use of nested studies within registries may be appropriate to satisfy the evidence requirements for a managed entry scheme. The managed entry scheme could provide conditional listing or a lower benefit until full listing is achieved. This may be particularly relevant in areas of high unmet clinical needs.

In relation to the 25% market share rule, the IWG considered whether a lower PL benefit could be based on sponsors' ability to deliver volumes equal to 25% of the market, rather than on their actual market share. This would allow the listed benefit to be based on the sponsor's potential to provide the threshold volume, and thus influence the market price, However in addressing this issue, PLAC may need to ensure that the grouping of categories are supportive of this mechanism.

In summary, the IWG agreed:

- that a PL be maintained to ensure consumers and clinicians can access a reasonable choice of clinically relevant prostheses, reimbursed by insurers, preferably without a consumer co-payment;
- that in setting a benefit for a device, consideration should be given to appropriate costs for inclusion in the benefit, including any clinically relevant requirements of the device (e.g. in-theatre assistance, software, maintenance/monitoring and product support etc.);
- that should Government seek medium term benefit reductions across the PL, it would be appropriate to consider legislating a price disclosure system for prostheses, encompassing both public sector and private sector medical device pricing;
- that reference pricing, taking into account domestic and relevant international prices, be considered as a mechanism to set the PL benefit;
- consideration should be given to establishing a mechanism to ensure service providers are reimbursed for the appropriate costs of maintaining inventory to encourage timely access to prostheses.

Identifying PL products or categories for immediate benefit rationalisation

The IWG considered analysis of data performed by the Chair and the Department, and noted that Prostheses List benefit levels for certain items are significantly higher than prices internationally. Publicly available data from Western Australia also indicated that PL benefits paid by insurers in the private system are inflated, in many instances, compared with prices in the public hospital system. It was reported to the IWG that the most obvious examples of inflated pricing, based on international and Western Australian public hospital data, was in the categories of:

- Cardiac – including single and dual chamber pacemakers, single and dual chamber implantable cardiac defibrillators (ICDs), ICDs with Cardiac Resynchronisation Therapy (CRT), CRT pacemakers, ICD and pacemaker leads and accessories, and coronary stents;
- Intra-Ocular Lens Systems (IOLs) – including anterior and predominantly posterior chamber IOLs;
- Hips – including both femoral and acetabular components and systems; and
- Knees – including femoral, tibial and patellar components and systems.

The data suggested that, in these four groups, the price differential is greater in cardiac and IOLs.

Subsequently, the IWG asked the Department to seek information from relevant sponsors on public and private sector pricing and incentives provided in respect of each of these categories. A request for information was sent to 57 sponsors, with 20 responses. A similar request was also sent to States and Territories, with responses from four jurisdictions. A copy of the information request is attached (Attachment D). It is important to note, however, that there has been no way for the IWG to verify the data received, and that there is no extant mechanism to audit the information.

A significant amount of commercial-in-confidence data and information was provided to the Chair and the Department during this process. Due to the nature of the information provided, it was not possible for the Chair to share this information with the IWG. While this report does not contain detailed data and analysis, the responses received clearly indicated that a price differential exists between public and private sectors. The IWG noted that the differential varies between and within categories. The IWG discussed that these differences may be related to purchasing power and the impact of exclusive contracts in the public system. The role of discounting by sponsors to achieve market share was also noted.

The IWG noted that some private hospital organisations have a similar magnitude of bargaining power to the public sector and that some private hospitals use their market power to achieve discounts or rebates on the PL benefit level. Bargaining power varies depending on the market size and location i.e. rural and remote of the hospital (where applicable), or day surgery. The IWG was advised that rebates offered to private hospitals are often provided in the form of a percentage across a suite of goods, including non-prostheses goods. Hospital representatives agreed that such rebating occurs, but contend that these rebates are used to cross-subsidise other activities, including medical devices and technologies (such as cardiac ablation therapy) which are not listed on the PL due to not meeting the current listing criteria. However, the IWG generally agreed that cross-subsidisation between non-transparent processes is a concern, and that better exposure of these processes through improved transparency is desirable.

In summary, the IWG agreed that the PL device categories of Cardiac, Intra-Ocular Lens Systems (IOLs), Hips and Knees appear to have the largest price-benefit differentials between the PL benefit and available domestic and international data, and that Government may wish to consider these categories as the initial targets for any benefit reduction. The IWG noted that benefit reductions may have relatively larger financial impacts on smaller companies, and recommended that these impacts be taken into consideration before benefit reductions are finalised.

Refining the scope of products on the PL, without compromising access

The IWG discussed in greater detail the current criteria for the PL. In particular, the IWG expressed views regarding the criteria in respect of the surgical implantation, and noted that as technology advances, new devices and technologies are being developed which do not specifically meet the PL criteria in this regard, but which are demonstrably safe, effective, and most importantly, cost-effective – in some cases with advantages to patients in terms of reduced hospitalisation and cost. While the IWG did not consider specific changes to the listing criteria, it did agree that listing criteria need to be flexible and dynamic, with the ability to list new technologies as they develop.

In summary, the IWG agreed:

- that if items are considered for removal in order to rationalise the PL, adequate time must be provided to allow new funding arrangements to be put in place;
- that further consideration is given to amending the PL criteria to include innovative medical technologies, which are demonstrably safe, effective and cost-effective but which don't meet the current PL criteria. This consideration should take into account the views expressed by the private health funds that this needs to occur in the context of a revision of the benefit setting

Opportunities for deregulation

The IWG discussed at length the composition and operation of the current PLAC. As discussed earlier, members agreed that both a PLAC and a clinical advisory structure should be retained, but that there are opportunities for changes to PLAC to enhance its deliberations. The IWG iterated its support for the PLAC Chair to continue to be independent, and considered that the committee could benefit from a refinement of members' skills mix to strengthen health economics expertise and cross-alignment with MSAC, with a view to better cost-effectiveness assessments of devices claiming clinical superiority. Membership of the committee must be considered to contain the range of expertise required to make informed decisions.

In this respect, the IWG noted that PLAC does not genuinely conduct cost-effectiveness analyses; rather, if a new device can demonstrate that it is clinically equivalent (non-inferior) to currently listed devices in the same group, then it will be listed at the group benefit. Use of the Superior Clinical Performance (SCP) suffix, which brings with it a benefit premium, is not well defined and would benefit from clarification and definition. The IWG recommends that the PLAC should develop guidelines describing the criteria for consideration of claimed superior efficacy across the Prostheses List. The IWG considered that an opportunity exists for better interaction and co-operation between PLAC and the TGA. There are also opportunities for PLAC to work with MSAC (and possibly other existing HTA bodies) to consider cost-effectiveness claims.

Within this context, the IWG affirmed its support for PLAC to have available to it expert clinical advice in relation to its functions, and recommended that further consideration be

given to the most effective structure of achieving this.

The IWG agreed there should be a formalised process of post-marketing review, which may lead to delisting of devices. The IWG considered this to be a major failing of the current PLAC arrangements, particularly when there is good evidence from registries that certain devices do not perform as well as their peers. The role of registries such as the Australian Orthopaedic Association National Joint Replacement Registry (NJRR). as an information source for PLAC was highlighted taking into account limitations of registry data The IWG considered that better feedback loops between registries and the PLAC would assist in identifying both superior and inferior devices – allowing assessments of a benefit premium in the former case, and delisting from the PL in the latter case. Any new post-marketing review process should require the PLAC to interact with the TGA in instances where safety and/or efficacy of devices are involved. The IWG noted that PLAC is not currently resourced to enable it to introduce a post-marketing review process.

In summary, the IWG agreed:

- that in the short-term, the Government should consider opportunities for enhanced co-operation between the PLAC and the TGA, to ensure that activities are not inappropriately duplicated;
- that PLAC should consider developing a routine process for assessment of devices for possible removal from the PL on clinical or cost-effectiveness grounds;
- that consideration should be given to revising the PLAC and its advisory committee arrangements, to:
 - ensure that committee membership is based on appropriate expertise;
 - maintain an independent Chair;
 - include a greater range of members on the PLAC, specifically:
 - additional health economics expertise
 - an expert member of the MSAC, to ensure alignment of related activities;
 - review the role of clinical advisory committees;
 - introduce the regular review of items on the PL and their PL benefits;
 - utilise existing HTA expertise as appropriate, for example the possible use of MSAC sub-committees to examine claims of clinical superiority in a cost effectiveness framework;
 - consider the role of registries, and interact meaningfully with current registries as part of listing and delisting processes;
- that Government should consider developing new PL Guidelines in respect of the listing process and the benefit setting process.

Ongoing interaction with stakeholders

The IWG considered that its deliberations had been helpful in providing information on the viewpoints of stakeholders. The IWG is of the view that it could be of assistance in the implementation and ongoing development of any reforms.

Conclusions

I present this report to the Department of Health as a summary of the outcomes of the deliberations of the IWG. I trust that the IWG's work will assist the Government further develop the prostheses listing and reimbursement processes to the benefit of all Australians.

As Chair of the IWG, I would also like to extend my appreciation to members of the IWG, who have debated and discussed many contentious issues during the IWG's term, and have assisted me greatly in facilitating access to information. I would also like to acknowledge the excellent support provided by officers of the Department to the IWG

Emeritus Professor Lloyd Sansom AO

Chair, Industry Working Group on Private Health Insurance Prostheses Reform

31 March 2016

Attachment A- IWG terms of reference

The role of the Industry Working Group on Private Health Insurance Prostheses Reform is to examine opportunities for reform of the arrangements governing prostheses and devices access and pricing in the private health insurance sector to ensure;

- Better access to prostheses and devices for consumers as part of the private health care offering;
- Reduced red tape and administrative burden for private health insurers;
- Opportunities for competition across the supply chain are maximised for the benefit of consumers and taxpayers.

In conjunction with the Department, the Group will assess the current system, including the Prostheses List Advisory Committee and Clinical Advisory Group processes.

The Group will advise the Department on a preferred reform option with a particular focus on:

- Creating a more competitive basis for the purchase and reimbursement of prostheses and devices, including consideration of options for implementing new pricing arrangements such as price referencing and price disclosure models;
- Identifying specific products or categories of products which may present opportunities for immediate benefit rationalisation;
- Refining the scope of products currently on the Prostheses List without adversely impacting on appropriate access for consumers; and
- Other opportunities for deregulation.

Membership

Members of the Industry Working Group on Private Health Insurance Prostheses Reform are appointed for their knowledge and expertise. Members will be required to sign confidentiality agreements and declare any real or potential conflicts of interests at the commencement of each meeting.

Timing

The recommendations of the Group will be considered by Government as part of a private health insurance reform package, with a view to commence implementation as part of the August 2016 Prostheses List.

The Group will meet in person or via teleconference on a limited number of occasions, in order to provide advice to the Department as soon as possible.

Attachment B – Membership of the Industry Working Group on Private Health Insurance Prostheses Reform

Name	Organisation
Professor Lloyd Sansom	Independent Chair
Rachel David	Private Healthcare Australia
Matthew Koce	HIRMAA
Susi Tegen	Medical Technology Association of Australia
Michael Roff	Australian Private Hospitals Association
Gabrielle Moreland	Australian Day Hospital Association
Leanne Wells	Consumers Health Forum
Ian Incoll	Royal Australasian College of Surgeons
Anne Trimmer	Australian Medical Association
Michelle Somlyay	Catholic health Australia
Georgina Sanderson	Cochlear Limited
Shane Porter	Department of Health
Adriana Platona	Department of Health

Attachment C:

The Prostheses List Guide (December 2015) provides the following information regarding the PL.

Medical device

The Therapeutic Goods Administration (TGA) defines a medical device as an instrument, apparatus, appliance, material or other article intended to be used for human beings for:

- diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or disability
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception.

Medical devices include a wide range of products, from those used externally (such as surgical gloves, bandages and condoms) to internal devices (such as pacemakers and dialysis equipment). Prostheses are a subset of medical devices. Safety and efficacy of medical devices are assessed by the TGA, and products must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be provided in Australia.

Medical service

Medical services include therapeutic, investigative and consultative procedures. When a surgically implantable prosthesis is provided to a patient, it is linked to a medical service. The evidence supporting the safety, effectiveness and cost effectiveness of the medical service is assessed by the Medical Services Advisory Committee (MSAC); the evidence supporting the clinical effectiveness and cost effectiveness of the prosthesis is assessed by the Prostheses List Advisory Committee (PLAC). Medical services that are subsidised by the government are listed on the Medicare Benefits Schedule (MBS).

Prosthesis

The types of prostheses covered by the Prostheses List are those that meet the criteria outlined below. Essentially, this is only those devices that are surgically implanted; or are essential to, and specifically designed as an integral single-use aid for, implanting such a product; or are critically important to the ongoing function of a surgically implanted product. Human tissue items such as corneas, bones and heart valves are also covered by the Prostheses List, as are insulin infusion pumps and cardiac loop recorders. External prostheses, such as external legs, external breast prostheses, wigs and other such devices are not included on the Prostheses List, and are not the subject of the arrangements covered by this guide.

Prostheses List Criteria

The *Private Health Insurance Act 2007* provides that benefits from hospital treatment cover will be paid in respect of a kind of prosthesis listed in the Prostheses Rules.

The criteria for listing a kind of prosthesis on Part A of the Prostheses List are as follows:

- 1) The product must be entered and current on the Australian Register of Therapeutic Goods
 - 2) The product must be provided to a person as part of an episode of hospital treatment or hospital-substitute treatment
 - 3) A Medicare benefit must be payable in respect of the professional service associated with the provision of the product (or the provision of the product is associated with podiatric treatment by an accredited podiatrist)
 - 4) A prosthesis should:
 - (a) be surgically implanted in the patient and be purposely designed in order to
 - (i) replace an anatomical body part; or
 - (ii) combat a pathological process; or
 - (iii) modulate a physiological process;
 - or
 - (b) be essential to and specifically designed as an integral single-use aid for implanting a product, described in (a) (i), (ii) or (iii) above, which is only suitable for use with the patient in whom that product is implanted
 - or
 - (c) be critical to the continuing function of the surgically implanted product to achieve (i), (ii) or (iii) above and which is only suitable for use by the patient in whom that product is implanted; and
 - 5) The product has been compared to alternative products on the Prostheses List or alternative treatments and
 - (i) assessed as being, at least, of similar clinical effectiveness; and
- (ii) the cost of the product is relative to its clinical effectiveness

Attachment D - Letter to sponsors requesting pricing data



Australian Government **Department of Health**

Dear Prostheses List Sponsor

Industry Working Group on Private Health Insurance Prostheses Reform Request for Information

The Department of Health has established the Industry Working Group on Private Health Insurance Prostheses Reform to examine opportunities for reform of the arrangements governing prostheses and devices access and pricing in the private health insurance sector. The Terms of Reference for the Working Group are provided at [Attachment A](#). Further information about the Working Group is available at [Industry Working Group Terms of Reference](#).

The Working Group has met on two occasions, 17 and 24 February 2016. Those two meetings have largely focused on the Terms of Reference requirement to identify “specific products or categories of products which may present opportunities for immediate benefit rationalisation”.

As Chair of the Working Group, I have been provided with information regarding prostheses pricing in the Western Australian public hospital system and internationally. With the agreement of all Working Group members, I am writing to seek the assistance of sponsors in gathering further information about prostheses pricing in Australia. With this information, I intend to provide advice to the Minister for Health, the Hon Sussan Ley MP, about how she might better relate benefits on the Prostheses List to actual public and private sector selling prices across Australia. The precise methodology for how this will be achieved is still under consideration by the Working Group, however I wish to give you as much notice as I can to prepare your response and input to our deliberations.

I am specifically seeking information to assist me to understand the net revenue for these products, taking account of all discounts/rebates/other direct or indirect purchasing incentives (collectively called “incentives” for this task). As such, I am asking that you provide information, in an Excel spreadsheet format, for items on the Prostheses List in the categories of cardiac, hips, knees, and intraocular lenses (as included in the attached spreadsheet) for which you are the sponsor. I am seeking, for the year to 31 December 2015 (or the closest possible 12 month reporting period) total revenue from sales of that item (GST exclusive) and the total volume sold in

- i. the public hospital sector, and
- ii. the private hospital sector.

A template spreadsheet is provided at [Attachment B](#), and is also being provided electronically. Due to the limited time to complete this request and in order to limit the impost on sponsors, I have included only the

major items in each of the four categories. If you wish to include additional information relating to other items in these categories, please do so in the spreadsheet.

A key consideration for this task is the identification of incentives. I am therefore also asking that you provide information relating to the total value of any incentives provided, including “off invoice”. Anything given as an incentive to purchase the prosthesis is relevant (whether the incentive was given before, during, or not paid until after, the relevant supply period; and regardless of who receives the incentive). This would include the value of incentives relevant to the particular item, across a range of items, or across an entire product range, including both Prostheses List and non-Prostheses List items. A list of possible incentives which may be applicable is at [Attachment C](#). This list is not exhaustive, and you may wish to include other incentives.

Where an incentive applies across more than one item, please apportion the value across all applicable items for the period. Given the limited time available, I am not being prescriptive about how to apportion incentives which apply across multiple items/products. However, I request that you are able to substantiate your chosen methodology if necessary.

In relation to this request, I would like to specify:

- Neither I, nor the Department of Health, have any power to compel you to provide the requested information. The provision of any or all of the requested information is entirely voluntary, however I believe that the provision of your data will provide a more holistic view of pricing patterns on which the Working Group can base its consideration of these issues.
- If there are pricing issues which you believe require further clarification or explanation, such as differing public and private sector circumstances, you may wish to provide this in the comments column or in a supplementary attachment.
- All information provided will be treated as commercial-in-confidence.
- Given the membership of the Working Group, I acknowledge the very real potential for conflicts of interest. As such, the information provided by individual sponsors will be provided only to the Department of Health and will not be provided to members of the Working Group. I undertake to consider whether a conflict of interest or breach of confidentiality would exist before any aggregated or summary data is provided to the Working Group. I have advised the Working Group that the information provided to them may be limited given these constraints.
- If you are unable to, or choose not to provide the requested information, I would be happy to receive any other information related to prostheses pricing which you believe would be relevant to the Working Group’s deliberations.

I would appreciate your response by 5pm 16 March 2016 by email to PHIConsultations2015-16@health.gov.au.

If you have any questions in relation to his request, please email PHIConsultations2015-16@health.gov.au

Yours sincerely

Authorised for electronic transmission

Prof. Emeritus Lloyd Sansom AO
Chair
Industry Working Group on Private Health Insurance Prostheses Reform
29 February 2016