APPLIED MEDICAL SUBMISSION TO COMPETITION POLICY REVIEW

INTRODUCTION

1. Applied Medical supplies, amongst other things, two models of laparoscopic clip appliers which are currently listed on the Prostheses List.[1] The Prostheses List regulates the prices of prostheses used in procedures involving private health subscribers. In 2013, Australians with private health insurance acquired prostheses at a value of approximately $1.6 billion.[2]

2. Applied Medical estimates conservatively that at least $592 million of this was unnecessary waste as a result of the inefficient regulatory structure that underpins the Prostheses List. Private Healthcare Australia, which represents private health insurers such as Medibank, Bupa, HCF, HBF and NIB, estimates that this unnecessary waste would be higher – at least $700 million.[3] Below we explain in more detail how this money would find its way ultimately to Australian health consumers (see section entitled "Money Merry-Go-Round").

3. In its Issues Paper the Panel identified two particularly relevant questions to consider in connection with the Prostheses List arrangements:

   (a) Would there be a net public benefit in encouraging greater competition and choice in sectors with substantial government participation (including education, health and disability care and support)?

   (b) Will more competition among providers serve the interests of consumers of health, education and other services?

4. The greatest driver of economic growth following the 1992 Hilmer Review involved the reform of regulations and other government policies which impeded competition. The core concepts emerging from that review included that:

   (a) Any regulations affecting a market should have a clearly identified policy aim;

   (b) Regulations available which achieve the public policy aim with the least possible economic distortion should be identified; and

   (c) The costs and benefits of the regulation should then be assessed and the regulation should only be adopted (or maintained) if the public benefits of achieving the policy aim outweigh the costs to society arising from the distortion.

5. These aims have not been achieved in relation to the procurement of prostheses in the private health system, despite several reviews of the Prostheses List arrangements.

[1] The Prostheses List is contained in Private Health Insurance (Prostheses) Rules issued by the Minister for Health under Section 333.20 of the *Private Health Insurance Act* 2007 (Cth).

[2] Private Health Insurance Administration Council (2013) *Industry Statistics*.

[3] Private Healthcare Australia (2013) *Submission to the National Commission of Audit*, p 2.

Those arrangements have contributed to serious distortions in the relevant markets, including that:

(a) The benefits set do not reflect the net prices actually paid for prostheses;

(b) The current method of determining group benefits restricts the ability of competitive and innovative prostheses suppliers to compete with incumbent suppliers, and is not consistent with the methodology at its inception (see para 32); and

(c) the benefits set, and even the net prices paid by hospitals for prostheses, are substantially higher than those found in comparable international markets and the Australian public healthcare system.

6. These distortions are the outcome of the perverse incentives created by the current regulatory structure, which has the effect of muting price competition between suppliers of prostheses in the private health sector. An additional issue is that the Prostheses List covers over 10,000 items, including a host of low-value consumables, which do not meet the usual definition of "prostheses" and which are not in need of such rigid price regulation.

7. In its Draft Report, the Panel echoed a suggestion by the National Commission of Audit that:[4]

> there is scope for "lighter touch" regulation of the private health insurance sector, which could encourage innovation and wider product availability for consumers.

8. The Prostheses List arrangements need to be reconsidered given the linkages between private health insurance premiums and the inputs (including prostheses). Indeed, in line with the concepts arising out of the Hilmer Review, it will be necessary to review whether the legislation and policy surrounding the Prostheses List still has a role to play and if so, whether there is an alternate form of regulation which would cause less distortion in the marketplace.

9. This submission details *what* needs reform, *why* this is the case and *how* reform can be brought about. In particular, it:

(a) Identifies the legal and policy framework surrounding the Prostheses List;

(b) Outlines the systemic issues associated with the methodology currently used to determine the benefits payable, which insurers, private health subscribers and government must ultimately pay, for prostheses on the Prostheses List; and

(c) Sets out the reforms, which are the subject of broad agreement amongst a number of industry participants, necessary to resolve these issues and bring about greater competition between suppliers of prostheses.

[4] Competition Policy Review, *Draft Report of The Australian Government Competition Policy Review* (September 2014), p 113

WHAT NEEDS REFORM: THE PROSTHESES LIST ARRANGEMENTS

10. The Prostheses List sets out those prostheses and devices which private health insurance policies must cover in order to comply with the *Private Health Insurance Act 2007* (Cth) (**the Act**).

11. The forerunner to the current Prostheses List had its origins in the New South Wales doctors' dispute of 1984. The List was part of a seven point package developed by the Penington Report to settle the dispute, and was intended to reduce hospital waiting lists for patients requiring procedures involving surgically implanted prostheses. It required the payment by insurers of a minimum benefit for a listed prosthesis, as determined by the Minister.

12. Prior to the Prostheses List, private patients in private hospitals were charged for prostheses and insurers were not required to reimburse the cost as part of basic insurance. By contrast, prostheses were provided free of charge to public and private patients in public hospitals. This had the effect of increasing the demand for public hospital services, which was at the centre of the doctors' dispute.

13. The Prostheses List in its current form was established in 2005 as part of wider reforms to the *National Health Act 1953* (Cth), in response to concerns regarding the increasing costs of prostheses and the resulting pressures on private health insurance premia. In 2007, further wide-ranging reforms were made to private health insurance which were intended to, inter alia, "enhance choice, certainty and the value of private health care" and support "improved information and services for consumers and greater competition in the insurance sector".[5] One of the primary objectives was to encourage consumers to take up private health insurance.[6]

14. Now, the Act provides the Minister for Health (**the Minister**) with the power to issue *Private Health Insurance (Prostheses) Rules*, which set out, inter alia, the benefits that private health insurers must pay in respect of particular prostheses – the so-called "Prostheses List".[7] The Minister's discretion in making a listing decision is broad.[8] Subject to the need to consult with stakeholders, there is sufficient power to implement reforms which would bring prostheses costs to the private health system down so that they would be comparable with prices paid in other countries – reducing prices by as much as 75%.

15. The Minister is assisted in his or her task by the Prostheses List Advisory Committee (**PLAC**), a non-statutory body of representatives from key stakeholders, clinicians and experts in health policy and economics. The role of the PLAC is supposed to be to advise the Minister about the listing of prostheses and their appropriate benefits by reference to: comparative qualitative clinical function and effectiveness; comparative

[5] Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth).

[6] Section 3.1 of the *Private Health Insurance Act 2007* (Cth).

[7] Section 333.20 of the *Private Health Insurance Act 2007* (Cth).

[8] The Act merely requires that the listing decision must provide for matters "required or permitted by the corresponding … Part" or "necessary or convenient … in order to carry out or give effect to that … Part"; see Section 333.20(1)(a)-(b) of the *Private Health Insurance Act 2007* (Cth).

cost effectiveness; comparative safety; and whether clinically relevant superiority compared to similar prostheses has been established.[9]

16. However, the PLAC process is structured in such a way that almost all its time is spent on the question of whether applications to join the list should be granted, and very little on setting efficient prices. Further, we understand that representatives of those device manufacturers who belong to the Medical Technology Association of Australia (**MTAA**) assert that all the information that would properly enable the PLAC and the Department to perform its function is "commercial in confidence" and therefore refuses to provide the information.

17. The PLAC lacks the power to collect the available information from public hospital procurement processes and has no resources to purchase international benchmark pricing reports such as IMS Health data from the US. The PLAC does not consider factors which would, on any view, be highly relevant to the proper assessment of the amounts which insurers should be required to cover in respect of particular prostheses, including:

    (a) the prices that device manufacturers charge private hospitals for prostheses in the real world;

    (b) prices charged for the same prostheses in the public sector; and/or

    (c) international pricing for the same prostheses.

18. In light of this, it is not surprising that the decisions made under the current regulatory structure have tended to discourage competition between, and encourage rent seeking by, suppliers, leading to the artificial inflation of benefits to the detriment of the private health insurance industry, private health consumers and the Australian Government. The formulation of the Prostheses List bears directly on the affordability of prostheses and ultimately the affordability of private healthcare for Australians.

THE MONEY MERRY-GO-ROUND

19. In paragraph 2 of this submission we have noted conservatively that the effect of this regulatory structure results in inflated costs for consumers of $592 million per year. This is the estimated annual average over-charge paid by private health insurers for listed items. The features of the regulatory system that enable this over-charging are detailed in the subsequent sections of this submission, but first this submission discusses how inflated prostheses prices are allocated between players in the market.

20. In consultations that Applied Medical has had with a range of parties about these issues, some stakeholders, although shocked by the size of the over-charge, have pointed out that part of this money is a "transfer" and that, if reform was undertaken, end consumer prices may not fall by the full $592 million.

21. Economists often talk about the transfers as the "square" and the efficiencies as the "triangle" - referring to the geographical depiction of these effects on a price/quantity

[9] Department of Health, *Appendix B – PLAC Terms of Reference and Business Rules*, Prostheses List Guide – Part 1, July 2010, p 58-6.

diagram. In fact, in this case there are several "squares" and "triangles", because there are multiple parties involved in the Prostheses List money "merry-go-round". These include:

(a) Medical device sponsors;

(b) Private hospitals;

(c) Public hospitals, when they treat private patients;

(d) Private health insurers;

(e) Consumers who subscribe to private health insurance;

(f) The Federal Government, through the private health insurance rebate;

(g) Insured patients who actually need private hospital treatment; and

(h) Players outside the private health system, including consumers who do not subscribe to private health insurance because it is made too expensive, Medicare and public hospitals treating public patients;

22. As observed by Deloitte Access Economics, principal-agent problems arise where private hospitals, who receive rebates, are responsible for selecting products the cost of which is borne by private health insurers and, through them, subscribers to private health insurance. This is exacerbated by the fact that, the higher a supplier's nominal benefit amount, the greater the rebate that supplier is able to offer.

23. The estimate of $592 million per year is the over-charge that would be saved if price signals were cost-reflective. However, questions arise as to who would gain or lose, and by how much. Two observations should be made:

(a) The first observation is that approximately one third of this saving would be money that is currently received by the private hospital as a hidden rebate to encourage the purchase of over-priced prostheses, a figure approaching $200 million. It can be expected that hospitals are at least to some extent changing their behavior in an inefficient way to obtain as much of this revenue as possible – this is a "triangle" or economic efficiency that would be recouped through reform as a true saving. On the other hand, much of the $200 million may currently be used by hospitals to cover other costs of providing health care efficiently. This may need to be recovered by the hospital through increasing other charges, and this would ultimately be borne by consumers. What we can also say with certainty about the "square" or transfer component is that to require private health insurers to pay billions of dollars for prostheses worth only hundreds of millions is an extremely roundabout way to deliver an operating cross-subsidy to other hospital activities of several hundred million dollars, and that if hospitals need this support it could be delivered to them directly and more cost effectively.

(b) The second observation is that the other two thirds of the savings would be money that is currently "cream" kept by device manufacturers in inflated prices net of the hospital rebate. A significant proportion of this $400 million or so

would be a "triangle" or efficiency. Reforms would enable the most cost-competitive suppliers to displace the unnecessarily expensive suppliers, creating true savings for the whole supply chain. However, it is acknowledged that some of this money is a "square" or a transfer from *Australian* consumers to *global* medical device companies. Unlike most "squares" or transfers, if reform is implemented much of this "square" will *not* need to be recovered in other ways through other charges ultimately met by Australian consumers. Most of this money is effectively a cross-subsidy from Australian consumers of prostheses to shareholders or consumers in other countries.

24. Equally, on the "other side" of the balance sheet there is a one third/two thirds split:

(a) Two thirds of the savings would accrue to private health insurers and in turn that would accrue to both those who are currently insured and those additional consumers who would be attracted to private health insurance once its costs reduce; and

(b) One third would accrue to the Federal Government in the form of reduced health insurance rebates which, in turn, could be used for spending on other healthcare, other social services or to lower the general tax burden.

25. The fundamental point here is that, whichever way the figures are "sliced and diced" the amounts are so large that *both* the true efficiency savings and the "mere transfers" are substantial in size. Additionally, a significant part of the cross-subsidies that are being masked through the deeply distorted effects in the market *can* be recovered as savings to the Australian health system if the system is reformed so that Australia pays only the fair world price for the items it consumes. Without reform, we simply cannot know for sure whether each of these money flows is in the high or low hundreds of millions but they are all worth seeking from the viewpoints of economic efficiency and equity.

HOW TO REFORM THE SYSTEM

(A) The benefits set do not reflect net prices actually paid for prostheses and encourage the provision of 'kickbacks'

26. As noted by the Panel in its Draft Report, "It is important that consumers have access to products that meet their needs, including in the area of private health insurance."[10] The benefits set for products listed on the Prostheses List are intended to ensure that insurers are required to cover the full cost of prostheses used in relevant procedures, and that private health subscribers are provided with suitable options which do not require the payment of an additional 'gap' amount.

27. Hospitals acquire prostheses on behalf of private health insurers and ultimately private health subscribers. To further the objectives of benefit-setting - i.e. to ensure coverage and cost minimisation for private health subscribers - private health insurers, and ultimately private health subscribers, should not be charged more for prostheses than

[10] Competition Policy Review, *Draft Report of The Australian Government Competition Policy Review* (September 2014), p 113

the cost incurred by the hospital. That is, benefits should be set at the level of the cost incurred by the hospital in acquiring any particular prostheses.

28. Instead, it has generally become the case that hospitals acquire prostheses from most suppliers at the amount that they will be reimbursed by private health insurers (i.e., the benefit amount) and demand substantial 'rebates' from medical device manufacturers. This disconformity between those responsible for making the purchasing decision (private hospitals) and those who incur the actual cost (private health insurers and ultimately subscribers) provides device suppliers with the ability and incentive to offer what can accurately be characterised as 'kickbacks'.

Case study: Laparoscopic clip appliers

The current benefit required to be paid by an insurer to a hospital where a laparoscopic clip applier is used in a procedure involving a privately insured patient is set on the Prostheses List to be **$412**.[11]

There are three significant suppliers of laparoscopic clip appliers in Australia – Johnson & Johnson, Covidien and Applied Medical – each with clip appliers listed on the Prostheses List.

Applied Medical has been informed by its customers that base rebates by other suppliers are up to 25% of the value of the benefit amount, effectively providing hospitals with a net price as low as 75% of the benefit, or **$309**. Additional rebates may be applied where a hospital exceeds growth or compliance targets.

Substantial rebating is so entrenched that standard supplier contract templates used by major hospital groups contain provisions dealing with the calculation, reporting and value of rebates.[12] Regardless of the rebate provided to hospitals by medical device manufacturers, those who actually pay, i.e. insurers, and ultimately privately insured Australians, receive none of the benefit of the rebate and instead are liable for the full benefit amount of $412.

Where suppliers do not provide rebates, they may charge a headline price below the benefit amount appearing on the Prostheses List. For example, in most cases, Applied Medical supplies its laparoscopic clip appliers at **$99** to private (as well as public) hospitals. In such cases, the hospitals still invoice insurers for $412, while only paying $99 for the product. However, out of concerns for possible 'external auditing', private hospitals have a strong preference for the rebating structure.

29. Deloitte Access Economics has observed that the differing incentives of participants in the market for prostheses (individuals, insurers, doctors, hospitals and manufacturers)

[11] The relevant subgroup on the Prostheses List is *03 General Miscellaneous – 03.08.03 Ligating Devices – 03.08.03.03 Clips with Disposable Applier – Laparoscopic.*

[12] An extract of these standard terms was provided at Attachment D to Applied Medical's submission dated 21 October 2014 to the Department of Health in relation to the February 2015 Prostheses List.

"mean that agency problems arise – in particular between doctors/hospitals ('agents') and insurers ('principals')":[13]

> Doctors/hospitals are effectively responsible for purchasing prostheses on behalf of insurers. However, insurers are unable to effectively monitor the actual cost of the prosthesis (as charged to the doctor). Further, insurers do not have the expertise or legal ability to mandate which prostheses are chosen in what circumstances.
>
> This lack of transparency and enforcement mechanisms means that surgeons and hospitals may have little regard to the interests of the insurers in purchasing prostheses on their behalf. Indeed, this market highlights the nature of principal-agent problems – even if an insurer knew that a doctor was making a self-motivated decision in purchasing an unnecessarily expensive prosthesis, they would still have no ability to do anything about it…
>
> These conflicting incentives are further exacerbated by volume rebates and other discounting arrangements negotiated between hospitals and suppliers.

30. In effect, the inflated minimum benefits charged to Australian health insurers, and ultimately private health subscribers, are 'divvied up' between the hospital and the device supplier via hidden rebates which generate a substantial surplus for the hospital and still result in the device supplier receiving much more than they would in other comparable countries.

31. Requiring insurers, and ultimately consumers, to pay more for prostheses than the costs hospitals incur for the purchase of these products has significant financial and reputational implications for the attractiveness of private health insurance. Further, it imposes upwards pressure upon private health insurance premiums and distorts proper efficiency incentives.

Possible reform: Pricing and rebate transparency

Introducing transparency around net prices is an important element in addressing the issues outlined above. Reform should involve the following elements:

- Hospitals and/or suppliers should be required to disclose actual (net) prices paid for prostheses.
- Disclosure could be required to either:
  1. PLAC, who could use the information when setting minimum benefits; or
  2. Insurers, who could be provided with a statutory right to only be liable for the lesser of the minimum benefit and the actual net price paid.
- It is also necessary to address the bundling of discounts and rebates.

(B) The current method of determining group benefits impedes the ability of competitive and innovative prostheses suppliers from competing with incumbent suppliers

[13] Deloitte Access Economics, *Economic review of the prostheses listing process* (October 2014), pp 10, 12.

32. In 2009, the Departments of Health and Finance undertook a review of Health Technology Assessment in Australia (**the HTA Review**), including of the Prostheses List arrangements. The Report of the HTA Review made a number of recommendations going to the rationality and efficiency of the existing structure, including that the negotiation of individual benefits for listed prostheses be abolished and that instead a single benefit be established for the products in each sub-group, with sponsors being required to accept this benefit in order to be listed. [14]

33. Further, the HTA Review expected that 'generally the single benefit will reflect the lowest benefit accepted for a product in a group'.[15]

34. Applied Medical understands that the PLAC originally intended to respond to the HTA Review by setting benchmark benefits for sub-groups on the Prostheses List according to the lowest benefit which a supplier in each sub-group was willing to accept. This would have been consistent with the recommendations of the HTA Review.

35. However, following lobbying from the Access Committee of the MTAA, which represents many of the incumbent medical device manufacturers, the 25% utilisation rate threshold was implemented:[16]

> "The Access Committee [of the MTAA] also successfully argued against the intention [of the Department of Health] to set benchmark benefits for Prostheses List products based on the lowest benefit accepted for a product in a group."

36. Applied Medical understands from discussions with a number of market participants and the Department of Health (**the Department**) that the rationale for the utilisation rate threshold was to ensure that prostheses supplied at the benefit level were:

- broadly clinically accepted in Australia; and
- supplied in quantities that would indicate the ability of the supplier to credibly supply a substantial percentage of the market.

37. These concerns would primarily arise in a 'worst case scenario' where other existing suppliers in a group chose to not supply at a new reduced benefit level. Based on Applied Medical's industry knowledge, such a scenario would be very unlikely to eventuate.

38. In practice, the 25% threshold has a number of important perverse effects.

39. As previously discussed, the difference between the benefits payable by insurers and the price at which the product would be supplied – absent the regulatory structure – is divided between medical device manufacturers and hospitals through the use of hidden rebates.

40. It follows that the higher a supplier's benefit above its actual cost of supply, the higher the rebate it can offer private hospitals. This has led to a situation where private

[14] HTA Review, *Review of Health Technology Assessment in Australia December 2009*, Recommendation 12.c.

[15] Ibid, p 94.

[16] Medical Technology Association of Australia (2011) *Annual Report 2010-11*, p 8.

hospitals have commercial incentives to select suppliers with the largest benefits set (who can thus provide the largest rebate to the hospital), instead of selecting suppliers with a lower benefit and possibly a more clinically effective product. This situation tends to increase costs for private health insurers and subscribers.

41. Customers have explicitly stated to Applied Medical that unless it also provides such hidden rebates or kickbacks, there is no incentive for the hospital to use its products. As a result of this situation, Applied Medical's sales to private hospitals remain restricted.

Case study: Laparoscopic clip appliers

In the Australian laparoscopic clip applier market, Applied Medical is broadly clinically accepted with a market share in excess of 25% in the public system.

The total demand for laparoscopic clip appliers in the Australian private healthcare system is only a small percentage of the total number of clip appliers supplied by Applied Medical globally. In the 12 months prior to 1 June 2014, Applied Medical supplied over 320,000 laparoscopic clip applier units globally.[17] Accordingly, Applied Medical could supply the entire Australian private healthcare system, if required, without significant new investment in production capacity.

Further, it is evident that other suppliers in this sub-group, such as Johnson & Johnson and Covidien, would not withdraw from supplying the market if the benefit were reduced. Each already supplies these products to private hospitals at a significant discount to the current benefit amount. Also, each of these suppliers supplies the same product to the public system at tender prices that are substantially lower than the amount that the Prostheses List sets for products provided to private patients.

According to information available to Applied Medical, clip appliers manufactured by Johnson & Johnson are sold to customers in the Victorian public system at prices between $195 and $229, while those manufactured by Covidien are sold for between $105 and $160.[18] Applied Medical's price in the same market is $99.

42. The current structure significantly impedes the ability of a supplier reluctant to engage in hidden rebating, such as Applied Medical, to reach a utilisation rate of 25% which is currently used to set the minimum benefit limit for the sub-group as a whole. As observed by Deloitte Access Economics, in markets for prostheses regulated by the Prostheses List, "[m]anufacturers may find it difficult to attract market share based on price leadership".[19]

[17] ***Confidential*** Internal Applied Medical SAP Accounts.

[18] Based on accrued Applied Medical market intelligence in advance of upcoming launch of relevant Victorian Government health tender.

[19] Deloitte Access Economics, *Economic review of the prostheses listing process* (September 2014), p 13.

43. The effect of this is that those suppliers who are able to more efficiently provide prostheses vis-à-vis existing suppliers are not able to benefit from an increase in market share as a result of normal competitive market forces, which would otherwise have generally produced such an increase. As a result, the 25% utilisation rate threshold actually acts to prevent innovation amongst suppliers to supply prostheses at lower costs to Australian patients, as the minimum benefit framework restricts the normal competitive market forces which would otherwise reward those suppliers with increased sales and market share.

44. This also means that the ability of an innovative, ethical competitor, willing to supply at a much lower benefit level, to influence the group benefit level, is severely restricted. Instead, the current structure, particularly the use of a 25% utilisation rate drawn from sales within the very same regulatory framework, serves to protect incumbents.

Possible reform: Remove 25% utilisation threshold

Removing the 25% utilisation threshold is one way to address the above issues. In summary:

- The PLAC currently looks to a utilisation rate test of 25% to determine the minimum benefit for each group. The test is intended to determine whether a supplier can credibly supply the private hospital system.
- The utilisation rate is set by reference to existing market shares in the private hospital system, effectively preventing newer, large and credible innovators from influencing the minimum benefit.
- The minimum benefit should instead be set at the price at which the lowest cost supplier is willing to supply the products, provided that supplier can demonstrate that they could credibly supply a substantial part of the market and that their products are clinically accepted as demonstrated by sales in either a private hospital market or a public hospital market.

(C) The benefits set, and even the net prices paid by hospitals for prostheses, are substantially higher than those found in comparable international markets and the Australian public healthcare system

45. The Prostheses List is intended to contribute to the Government's objective of making private health insurance more attractive to consumers. This can only be achieved by ensuring that private health insurance is competitive with alternatives enjoyed by consumers, such as the public health system. It is important to recall, in this context, that a key part of the genesis of the Prostheses List in the 1980s was that consumers were finding it cheaper in many cases to attend a public hospital instead of attending a private hospital.

46. In relation to prostheses, consumers pay more (albeit indirectly through their insurers) for prostheses in procedures under private health cover, than if they had the same procedure in the public system. Importantly, consumers must pay the full benefit amount through their insurers. Neither consumers, nor their insurers, are entitled to, or receive, any of the significant rebates provided to hospitals.

47. The table below sets out the comparative cost to those who incur the financial cost of prostheses when patients are treated as private and public patients. This highlights the fact that those who ultimately pay for prostheses pay up to four times more for the same prostheses in the private system as in the public system.

Case Study: Laparoscopic Clip Applier Cost to Payer in Australia			
	Applied Medical	**Johnson & Johnson**	**Covidien**
Private patient private hospital, nationally	All models $412	All models $412	All models $412
Public patient public hospital, Western Australia[20] (2010)	All models $99	JJ482 - $364 JJ186 - $364	AS073 – $331.27 AS074 – $383.85 AS137 - $419.61
Public patient public hospital, Victoria[21] (2014)	All models $99	JJ482 – $229 JJ186 - $195	AS074 - $105 AS137 - $160
As Applied Medical has expanded operations in Australia, competitors' pricing has significantly dropped in the public sector as demonstrated by recent public tenders. Covidien has more than halved the price of its laparoscopic clip applier from the time of the 2010 Western Australian tender to the most recent 2014 Victorian tender. Johnson & Johnson has similarly significantly reduced its price.			

48. Another salient objective of the Prostheses List is to limit the growth in the cost of prostheses in absolute terms and to reduce the pressure on health insurance premiums that has resulted from significant increases in prostheses expenditure in past years. It is therefore important to consider whether the current regulations assist insurers and private health subscribers in achieving value for money.

49. International pricing provides a useful comparator. While it is certainly the case that some products are priced differently in different countries, in competitive markets, these price variations should generally be limited to the additional costs that are incurred in the Australian market vis-à-vis the comparator country.

50. A comparison of amounts charged for prostheses by the same supplier in other markets with the prices being charged in Australia should be indicative of the additional costs of doing business in Australia. If this is not the case, it is cause for investigation as to why the business is able to sustain higher prices in Australia.

[20] See WA Health Corporate Network, *Contract HCNS109009 (Disposable Surgical Instruments): Pricing Information Schedule*, Item References 1392-1935.

[21] Based on accrued Applied Medical market intelligence in advance of upcoming launch of relevant Victorian Government health tender.

51. Private Healthcare Australia has investigated this issue and found that:[22]

> Legislated benefits payable for prostheses in Australia are up to five times higher than the prices paid in comparable economies, such as the United States and United Kingdom. In 2011-12 the total benefits paid by private insurers for prostheses was $1.5 billion (approximately 14% of all benefits paid).
>
> If prostheses benefits were aligned to levels in comparable economies abroad, the Federal Government would save "around $241 million per year instantly from the contributions it makes to the cost of private health insurance premiums" via the Australian Government Rebate.[23]

52. Indeed, Applied Medical has found that the prices charged to Australian consumers of laparoscopic clip appliers are far higher than prices in comparable overseas economies.

Case Study: US Average Selling Prices for Laparoscopic Clip Appliers

Supplier	Supplier Catalogue Code	Billing Code on Prostheses List and Product Name	US Average Selling Price* in USD	Exchange Rate Adjusted in AUD[24]
Applied Medical	CA090	MH014 Direct Drive 10mm Clip Applier	$84.39	$96.36
	CA500	MH015 Epix 5mm Clip Applier	$87.52	$99.76
Covidien	176615	AS074 Endoclip 10mm Clip Applier	$101.60	$116.20
	176620	AS073 Acuclip 5mm Clip Applier	$173.89	$198.56
	176630	AS137 Endoclip III 5mm Clip Applier	$174.43	$199.18
Ethicon (J&J Subsidiary)	EL5ML	JJ482 Ligamax 5mm Clip Applier	$154.35	$176.25
	ER320	JJ186 Ligaclip 10mm Clip	$90.13	$102.92

[22] Private Healthcare Australia, *Submission to the National Commission of Audit (Health and related expenditure)* December 2013, p 2; accessible via the National Commission of Audit website: http://www.ncoa.gov.au/docs/submission-private-healthcare-australia.pdf

[23] Private Healthcare Australia, *Submission to the National Commission of Audit (Health and related expenditure)* December 2013, p 2.

[24] Based on USD/AUD exchange rate as of 20 October 2014.

		Applier		
	ER420	JJ186 Ligaclip 12mm Clip Applier	$92.09	$105.16

- It is clear that Applied Medical can supply its laparoscopic clip appliers in Australia for $99 which it currently does so throughout the public and private sectors. The table above shows that, exchange rate issues aside, the variation between its US and Australian selling prices is less than $15. Any additional costs of supplying these products in Australia must, as a matter of commercial sense, be less than $15.

- Even if J&J and Covidien had significantly more inefficient local Australian operations compared to Applied Medical (which is unlikely given their size and scale), it is apparent that the differences in pricing between the US and Australia cannot in itself be explained by higher costs of supply that occur in the Australian context.

53. A regulatory structure which results in prostheses prices for privately insured Australians being multiple times higher than in the Australian public sector, and as much as five times more expensive than in comparable international economies, discourages Australians from choosing private health insurance over alternative options and reduces the attractiveness of private health insurance overall.

54. Accordingly, the resulting effect of the regulatory structure is not only to mute the pressures of competition between suppliers, making the market anti-competitive, but also to detract from a most important policy objective – i.e. to encourage the uptake of private health insurance. Allowing the cost of a substantial determinant of health insurance premiums to be up to five times higher than required seriously impedes the ability of the Prostheses List system of regulation to meaningfully contribute to making private health insurance more attractive to consumers. Indeed, it may have the reverse effect.

Possible reform: Benchmark pricing

Benchmark pricing is one way to address the above issues.

In setting the minimum benefit for each group, the PLAC could be required to have regard to a benchmark figure for each product. The benchmark should be a composite of a number of sources and could include:

1. International average net selling prices (after adjustments made against any discounts and rebates);
2. Average selling prices in Australian public hospitals;
3. The value of rebates and discounting; and/or
4. An optional “standing public offer.”

(D) The Prostheses List now includes a substantial number of products which are not generally considered to be 'prostheses' and for which there is little justification for such rigid price regulation

55. It is important to recall the original purpose of the Prostheses List. This can be found in the Penington Report recommendations which were adopted by the Government of the day, and the Second Reading Speech upon which Parliament passed the implementing legislation. It is clear that the list was intended to provide incentives for Australians to take up private health insurance by including in their coverage the cost of those products which were:

    (a) "in the advancing edge of their discipline";

    (b) "surgically implanted";

    (c) expensive, to the point where its cost would be determinative of the cost effectiveness of the operation; and

    (d) for which private patients would be otherwise "in many situations … willing to pay the full cost."

56. The Prostheses List has grown to encompass a very substantial number of products which do not meet these criteria.

57. There has been some criticism that many products on the Prostheses List (such as insulin pumps) would not generally be considered to be prostheses, as the medical profession understands that term. Many of these products would also not appear to even meet the broad criteria applied by the PLAC as detailed in the Prostheses List Guide to Listing and Benefits for Prostheses.

58. For example, on no basis could insulin pumps be considered a prosthesis under either the ordinary definition of the word, or in light of the broader criteria adopted by the PLAC. According to the Report of the 2009 HTA Review, the then Health Minister (the Hon Nicola Roxon MP) had requested that these remain on the Prostheses List *notwithstanding* they were not "prostheses" in the sense of a surgically implanted device, or even a device which was integral to the use of a surgically implanted device.[25]

59. A greater concern is that the Prostheses List has grown to encompass products which may be surgically implantable devices, or devices integral to the use of such devices, but which Parliament never intended the Minister to regulate. For example, the following sub-groups contain low value surgical consumables, which clearly do not meet the criteria considered by Parliament when the regulation of prostheses was first adopted:

    (a) 03.08.03.01 (ligation clips);

[25] HTA Review, *Review of Health Technology Assessment in Australia* (December 2009), Appendix G, p 165. The Report also notes that the previous Health Minister (the Hon Tony Abbott MP) had sought to introduce additional criteria limiting the scope of the Prostheses List.

(b) 03.08.04.01 (staples (non-bone));

(c) 03.08.05 (various sizes of polypropylene/polyester mesh);

(d) 06.03.05.01 (wires);

(e) 06.03.05.02 (pins);

(f) 06.03.06.01 (staples);

(g) 07.01.07.07 (clamps); and

(h) 03.08.03.03 (clips with disposable applier) – laparoscopic.

60. While it is inherent in a framework such as this that some products will fall into a grey area as to whether they meet the relevant criteria, it is clear that the Prostheses List now encompasses many products which are incompatible with the intentions of Parliament as to what these regulatory powers were intended to encompass.

61. In light of the above, there is a serious question as to whether many products currently on the Prostheses List should be regulated at all and why market forces should not be given a fuller reign, at least where:

(a) the product is of low-value and relatively "commoditised"; and

(b) the product is unlikely to determine the overall cost effectiveness of the surgical procedure.

Possible reform: Remove non-prostheses from the Prostheses List

There should be clear and logical criteria as to what should and should not be on the Prostheses List, which contains over 10,000 devices. For now, it should be noted that:

- The definition of what a Prostheses is for the purpose of determining whether a medical device can be listed is artificial. Further, it is largely at the Minister's discretion as to whether or not to make decisions in accordance with those criteria (noting there are some very basic legislated criteria he or she must follow).

- If a medical device is not listed on the Prostheses List, particularly a low value commoditised device, responsibility for funding transfers to the private hospital to be drawn out of standard, procedure-based funding. This transfer of responsibility to more efficient markets will improve pricing outcomes.

- This would also significantly reduce the costs associated with regulating the Prostheses List.

CONCLUSION

62. The policy aims underpinning many aspects of the Prostheses List arrangements are unclear. Indeed, despite significant reviews of these arrangements many aspects of the current regulatory system have developed in an *ad hoc* manner without proper consideration of their effect on prostheses markets.

63. In other areas, it is possible to identify a policy rationale; for example, ensuring that products have reached an appropriate level of clinical acceptance. However, as this submission seeks to demonstrate, it is doubtful whether the marginal policy gains achieved by these measures are justified by the distortions they create. In any event, there exist suitable regulatory alternatives.

64. Indeed, it is Applied Medical's view that it is necessary to consider each of the reform elements described above in order to address the anti-competitive issues endemic to the Prostheses List while furthering the goals of the regulatory framework.

65. For example, an analysis of net pricing to private hospitals in Australia would not reveal the competitive price that the product would be supplied at had the benefits not been divvied up between the private hospital and the medical device supplier.

66. Instead, each of the reform elements informs the others and contributes to a more efficient competitive prostheses market for private hospitals that furthers the Government's stated and ideological goal of increasing the uptake of private health insurance in Australia.

67. Our recommendations are as follows:

    (a) introduce transparency around net prices by requiring hospitals and/or suppliers to disclose actual (net) prices paid for prostheses;

    (b) remove the 25% utilisation threshold to determine the minimum benefit for each group;

    (c) have regard to a benchmark figure for each product in setting the minimum benefit for each group; and

    (d) remove non-prostheses from the Prostheses List.

Deloitte Access Economics

Economic review of the prostheses listing process

Applied Medical

October 2014

Deloitte.

Deloitte Access Economics Pty Ltd
ACN: 149 633 116

Level 7, 225 George St
Sydney NSW 2000
PO Box 6334
Kingston ACT 2604

Tel: +61 2 9322 7000
Fax: +61 2 9322 7001
www.deloitte.com.au

Nick Taylor
Partner
Jones Day
Level 41, 88 Phillip Street
Sydney NSW 2000

15/10/14

Dear Nick,

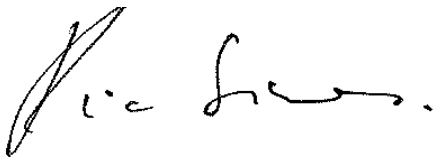
Economic Review of the Prostheses Listing Process

Thank you for asking Deloitte Access Economics to prepare a report on the economic review of the prostheses listing pricess. I am pleased to present our report to you.

The conclusions presented in this report are wholly or substantially based on our knowledge, training and experience as economists, the data and information provided to us and our consideration of factors that we believe are relevant. Where we have relied on advice provided to us by Jones Day or other sources of information, we have identified these to the best of our ability through the document.

While we understand that this report will be utilised for the purpose of informing policy and regulatory decisions, we acknowledge that we have read, understood and taken into account the Federal Court of Australia's Practice Note CM 7, Expert Witnesses in Proceedings in the Federal Court of Australia. We have made all inquiries that we believe are desirable and appropriate to answer the questions put to us. No matters of significance that we regard as relevant have to our knowledge been withheld. We have been provided with a copy of the Federal Court of Australia's Guidelines for Expert Witnesses in Proceedings in the Federal Court of Australia, and confirm that this report has been prepared in accordance with those Guidelines.

Yours sincerely,



Ric Simes
Director
Deloitte Access Economics Pty Ltd

Contents

Tables

Figures

Glossary

DAE	Deloitte Access Economics
PDC	Prostheses and Devices Committee
PLAC	Prostheses List Advisory Committee
TGA	Therapeutic Goods Administration

1 Introduction

Deloitte Access Economics has been asked by Jones Day, acting on behalf of Applied Medical, to undertake a report reviewing the efficiency of the prostheses listing process in Australia, for the purpose of use in submissions by Applied Medical and/or Jones Day to inform regulatory and policy decisions. This is not intended as an expert witness report.

The specific scope of work is set out at Appendix B. In broad terms, Deloitte Access Economics has been asked to:

- provide a general framework for analysing the market for the supply of medical devices including discussing the market mechanism and any public policy considerations which might arise in this particular market;
- identify the relevant markets in which prostheses devices, medical services and insurance are provided;
- identify the most significant economic effects of the current regulatory decisions with respect to the prostheses traded in markets relevant to Applied Medical; and
- discuss the economic principles which should guide decision-making under the current regulatory framework, and any implications for what particular grouping or minimum benefit level should apply to Applied Medical's products.

This report is structured as follows. Chapter 2 sets out the legislative and regulatory context for the listing of prostheses. Chapter 3 provides a framework for analysis and discusses the potential implications for competition and health care policy of the current framework. Chapter 4 discusses what economic principles should guide decision-making under the current regulatory framework and what an alternative regulatory framework could look like.

2 Evolution of the regulation of prostheses in the private health system

Prostheses are important in the provision of quality health services. Choice of prostheses can vary in importance depending on their clinical function. For example, prosthestic limbs and joints can significantly affect an individual's quality of life; whereas other prostheses are likely to have minor impacts,for example, those that aid in surgery.

As the markets for provision of prostheses to private patients in Australia currently operate, incentives for some market participants are skewed. This can be attributed to two main causes:

- a highly regulated market; and
- a supply chain complicated by different levels of aggregation.

Hospitals seek to attract surgeons to operate within their facilities. Within this framework, they seek cost-effectiveness, and thus face an immediate incentive to maximize their margins. This can be achieved either through increasing negotiated rebates and/or discounts; or maximizing minimum benefit amounts.

The latter creates an adverse long-term effect. Insurers have a potential role in helping consumers to solve a difficult information and bundling problem. However, insurers are unable to monitor differences between minimum benefits and actual net (after rebate/discount) prices paid by hospitals. Further they are prohibited from negotiating with hospitals on prostheses charges to capture some of these margins. Depending on the level of cross-subsidisation, this may result in private health insurance premiums being higher than they otherwise should be.

Ultimately, the regulation of "sticker" or headline prices through the current minimum benefit setting process has created adverse incentives and clouded market mechanisms – a result which is common in markets where prices are regulated. As noted by the Productivity Commission (2005), there is evidence that this can have large impacts.

The market operates at different levels of aggregation. Specifically, the relationships and contracts between patients and insurers; insurers and hospitals; and hospitals and manufacturers occur at different levels. Patients contract with insurers on an individual level. Insurers may negotiate aggregate contracts with hospitals in some instances, but hospitals charge insurers on an individual patient basis. Contracts between hospitals and manufacturers are generally aggregate, covering a number of different products, some of which may not be listed on the Prostheses List. Manufacturers offer bulk discounts or rebates to hospitals. This clouds information through the system and distorts price signals (since discounts and/or rebates are not generally disclosed on a line-item basis).

This complexity is not unique to the markets for prostheses. For the results of these markets to be efficient, effective competition – or, at the least, appropriate incentives – throughout the supply chain are required. However, the combination of individual prostheses being, in some instances, a small part of the overall cost of services, and the high level of regulation in the market, mean that incentives are currently not well aligned.

2.1 Legislative and regulatory context for listing prostheses

Under the Private Health Insurance Act 2007, private health insurers are required to pay mandatory minimum benefits for a range of prostheses that are provided as part of an episode of hospital treatment (where a Medicare benefit is payable for the associated professional service). The kinds of prostheses covered are set out in the Private Health Insurance (Prostheses) Rules. The list of prostheses set out in these rules is known as the Prostheses List.

In order for a medical device supplier to get its product placed on the Prostheses List, it must apply to the Minister for Health. The Prostheses List Advisory Committee (PLAC), in turn, advises the Minister on the listing of prostheses and their appropriate benefits.

While insurers are required to pay minimum benefits for the use of any prostheses on the list, the choice of prostheses is typically made by hospitals and surgeons. In sourcing prostheses, hospitals may be offered a discount relative to the minimum benefit or may receive rebates based on the volume of prostheses and/or other products sold. In both cases, the insurer is still required to pay the full minimum benefit amount for prostheses, without the ability to directly access the discount and/or rebate offered to the hospital.

2.1.1 The policy purpose of providing a minimum benefit

The cost of supplying prostheses is a substantial component of total hospital benefits paid by private health insurers. Over the year to March 2014, expenditure on prostheses by private health insurers was $1.7 billion or 14% of total hospital benefits paid (Private Health Insurance Administration Council 2014).

Prostheses costs also constitute a significant proportion of expenditure by public hospitals. While limited information is available on the costs of prostheses in public hospitals, the Productivity Commission (2009) notes that average prostheses costs in public hospitals are lower, averaging $131 per casemix-adjusted separation compared with $542 in private hospitals.

However, the two figures are not strictly comparable. The Productivity Commission notes that care needs to be taken in interpreting these figures as they could reflect both bulk-purchasing arrangements in the public sector as well as the wider range of higher-priced products available in the private sector.

The policy rationale for establishing a minimum benefit was to provide a price cap so as to control growth in the cost of prostheses over time. Previous arrangements, which were introduced in February 2001, required insurers to individually negotiate benefits with sponsors for all prostheses used, with insurers not being permitted to charge patients any

out-of-pocket costs for prostheses. This led to rapid growth in prostheses costs with benefits per prosthesis almost doubling between 2000-01 and 2002-03 (Doyle Review, 2007).

As a result, the government introduced reforms under the National Health Amendment (Prostheses) Act 2005 to require that insurers pay a minimum benefit for a more limited range of no gap prostheses which were available for every in-hospital procedure on the Medicare Benefits Schedule. Insurers could also offer a range of more expensive prostheses, but could not pay benefits less than the minimum amount listed or more than the maximum amount listed for a gap-permitted prosthesis.

This option was introduced with the aim of reducing private health insurer costs by requiring them to only cover the cost of no-gap prostheses in full, rather than all prostheses. It was also expected to reduce the administrative costs for insurers of negotiating benefits for all prostheses on the list. This was expected to reduce the pressure on health insurance premiums over time (National Health Amendment (Prostheses) Bill 2004 Explanatory Memorandum).

One option noted in the Bill's explanatory memorandum was deregulation of the market. This would have allowed insurers to choose to offer products which cover prostheses, with or without gaps, and provide information on the level of coverage for each product. However, concerns were raised that this could reduce the range of prostheses available to consumers, increase uncertainty for consumers in relation to what prostheses they were covered for and increase negotiation costs for suppliers.

Since 2005, expenditure on prostheses per treatment episode has grown below the rate of inflation (Medical Technology Association of Australia 2013), which suggests that the reforms have played a role in limiting the rate of growth in prostheses prices, noting that it is difficult to know what the outcome might have been under a more deregulated market. However, despite a slower rate of growth, the costs of prostheses in Australia remain high relative to other countries. This suggests that there is still significant room for improvement.

2.2 Findings of the HTA Review

In 2009, the Review of Health Technology Assessment in Australia (HTA Review) made a number of further recommendations in relation to prostheses regulation in Australia. These included:

- changing the terms of reference of the Prostheses and Devices Committee (PDC) and broadening its membership;
- abolishing the negotiation of benefits for individual listed products (which was very resource intensive) and instead establishing and maintaining a single benefit for the products included in each group, with sponsors required to accept this benefit to be listed;
- abolishing the setting of maximum benefits to eliminate gap payments; and
- allowing the establishment of new product groups where a sponsor establishes clear superiority of their product compared to those in an existing group.

2.3 Implementation of the HTA Review recommendations

In 2010, the Federal Government endorsed many of the HTA Review's recommendations. Since then, implementation of these recommendations has begun; however, there has been a lag in implementation. Further, issues have arisen with the method through which HTA recommendations have been implemented, meaning that the vision espoused by the HTA Review has not (yet) been fully realised.

The government responded to the recommendations of the HTA Review by replacing the PDC with the Prostheses List Advisory committee with a broader membership.

The HTA Review intended to create clean categories and groupings of prostheses which are clinically equivalent or have similar clinical effectiveness. This recommendation has largely been implemented through PLAC's establishment of minimum benefit prostheses groups. However, in some cases, implementation has been done in such a way that the resulting grouping does not meet the intentions of the Review. For example, until August 2014, prostheses in the class 03.08.03.03 with the suffix 'Endoscopic' were not clinically equivalent. This problem was acknowledged by PLAC.

Once these groups were established, the aim was to progressively move to establish a single benefit for products in each group, as noted above, with all sponsors in that class required to accept the minimum benefit amount listed. The PLAC sought to implement this recommendation by setting uniform minimum benefits for a class based on a 25% utilisation rule. Under this rule,

> *"the methodology used to determine appropriate group benefits fixed the benefit price at a point where 25% of a group's utilisation had a listed benefit at or below that point."*

This methodology was not recommended or endorsed by the HTA Review. Its operation in recent years has produced unintended consequences. These are described in more detail in Section 4.1.1 below.

The process used to determine these minimum benefits has also unintentionally created adverse incentives. Advice provided to Deloitte Access Economics from Jones Day suggests that:

- prices are more 'sticky' than what would ordinarily arise in a market, and there is a tendency towards maintaining an established minimum benefit level. Manufacturers have to make a submission to PLAC if they wish the minimum benefit level to be revised. As an example, in the class 03.08.03.03, the $412 minimum benefit has persisted for a number of years, despite the list being revised approximately twice each year.
- minimum benefits provide a starting point for negotiations with hospitals about price, although they may not reflect actual prices.
- anecdotal evidence suggests that sponsors which are establishing a new group are able to request a given price, and there is little active negotiation over this price. New joiners to that group can then simply leverage the higher price initially established.

This is counter to what is ordinarily seen in competitive markets, where new players will tend to introduce more price competition, thus decreasing prices over time.

These outcomes are not what would be expected in an unregulated competitive market. Ordinarily, theory would suggest that prices and quantities traded will be responsive to changes in demand and supply, and prevailing prices for goods of a similar purpose and quality in the same market would be the lowest price at which a supplier was willing to sell.

Figure 2.1 illustrates how this has played out in practice in the market for clip appliers. It shows that the vision espoused by the HTA review has not (yet) been fully realised, as there have been times when differential minimum benefits have been set for products which are clinically similar or equivalent.

Figure 2.1: The case of clip appliers

Applied Medical has a number of products, including two products currently on the prostheses list in the category 03.08.03.03 with the suffix 'Laparoscopic'. These products are the Direct Drive laparoscopic clip applier with TiGold titanium clips and the Epix™ Disposable Laparoscopic Clip Applier with TiGold M/L titanium clips.

The benefit provided for this group has changed over time. In the August 2012 Prostheses List, the benefit for all products on this list was $412. This calculation was based on fixing the benefit to a point where 25% of a group's utilisation had a listed benefit at or below that point, based on product utilisation data from May 2009 to May 2009. Some products on the list previously had a benefit of $142.

The Department of Health subsequently recalculated the benefit based on data from 2011-12, recommending that the benefit for clips with disposable appliers be adjusted to $145. However, various sponsors raised concerns in relation to the creation of a single group benefit (Department of Health 2013) and the Department noted that more work was needed to investigate the comparative clinical effectiveness of products in the group.

As an interim measure, the group was divided into two benefit levels with some products retaining a benefit of $412 whereas others were listed at $145. Jones Day has advised that these divisions were derived based on the original group benefits nominated by suppliers. This is inconsistent with the recommendations put forward by the HTA Review on grouping, price uniformity and lowest cost.

In the February 2014 Prosthesis List, the minimum benefit for both of Applied Medical's products was $145, while products with a similar clinical function produced by Johnson and Johnson and Covidien were listed with a minimum benefit of $412. The minimum benefit for Applied Medical's products was subsequently revised to $412 in August 2014.

3 Framework for analysis

3.1 The relevant markets

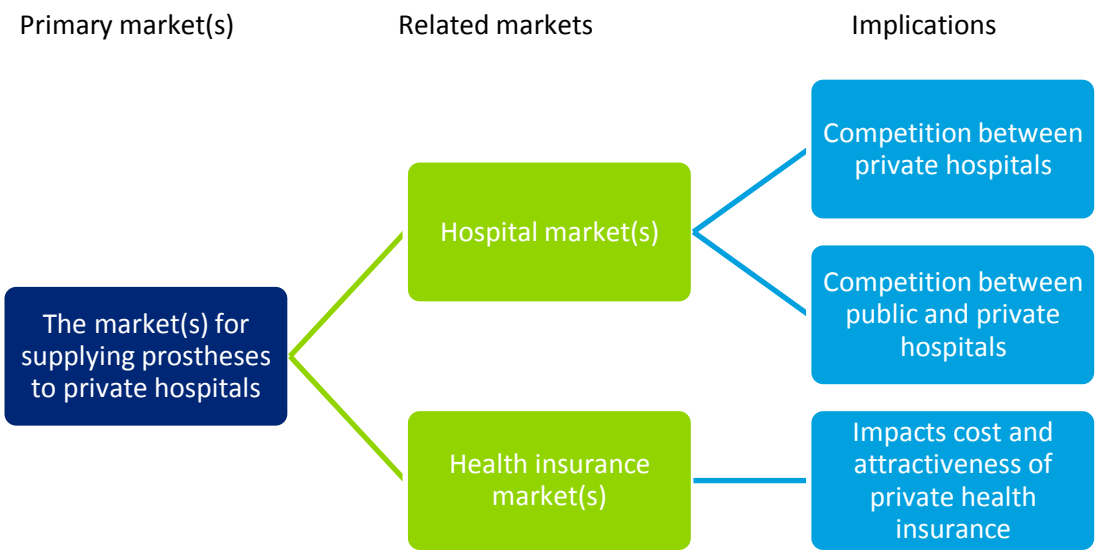
Markets for supplying prostheses in Australia have a variety of characteristics. These can be defined by:

- The system they are supplying – procurement processes are significantly different between private and public patients, due to regulations governing provision of choice and minimum benefits for privately insured patients
- The purpose of the prostheses – there are many different types and classes of prostheses, most of which are used for different clinical purposes and are not substitutable
- The clinical effectiveness of the prostheses – prostheses used for the same clinical purpose may offer varying levels of quality. This may affect the their substitutability

In the private system, the grouping of devices into minimum benefit groups has the effect of (artificially) defining markets. Prostheses within a group have the same clinical purpose and comparable clinical effectiveness; if clinical superiority can be demonstrated, a particular sponsor can apply to be moved to a different group. As such, under the assumption that grouping is achieved in accordance with these principles, products within a group can be considered closely substitutable.

Prosthetic device manufacturers typically supply their products to hospitals or surgeons. This has the potential to affect a variety of other related markets. The impact on other relevant markets is illustrated in Figure 3.1 below.

Figure 3.1: Implications for other markets



Source: Deloitte Access Economics.

Figure 3.1 indicates that the market(s) for supplying prostheses to hospitals and surgeons in turn affects competition in two other markets. First, differences in the cost of prostheses can potentially affect competition in the hospital market, including between different private hospitals who may have different agreements with prostheses suppliers.

The cost of supplying prostheses in the primary market and the prostheses chosen can also affect the benefits paid by insurers who cover these prostheses. This can create upward pressure on health insurance premiums, which in turn can affect the attractiveness of private health insurance to consumers. If the attractiveness of private health insurance declines, this will lead to more consumers choosing to rely solely on the public health system for health care.

3.2 Implications for competition and health care policy

In order to determine the impacts of the regulatory prostheses listing and pricing process on competition and market outcomes, it is first necessary to understand the counterfactual – that is, how a free and competitive market based on the market mechanism would operate in the absence of any regulation.

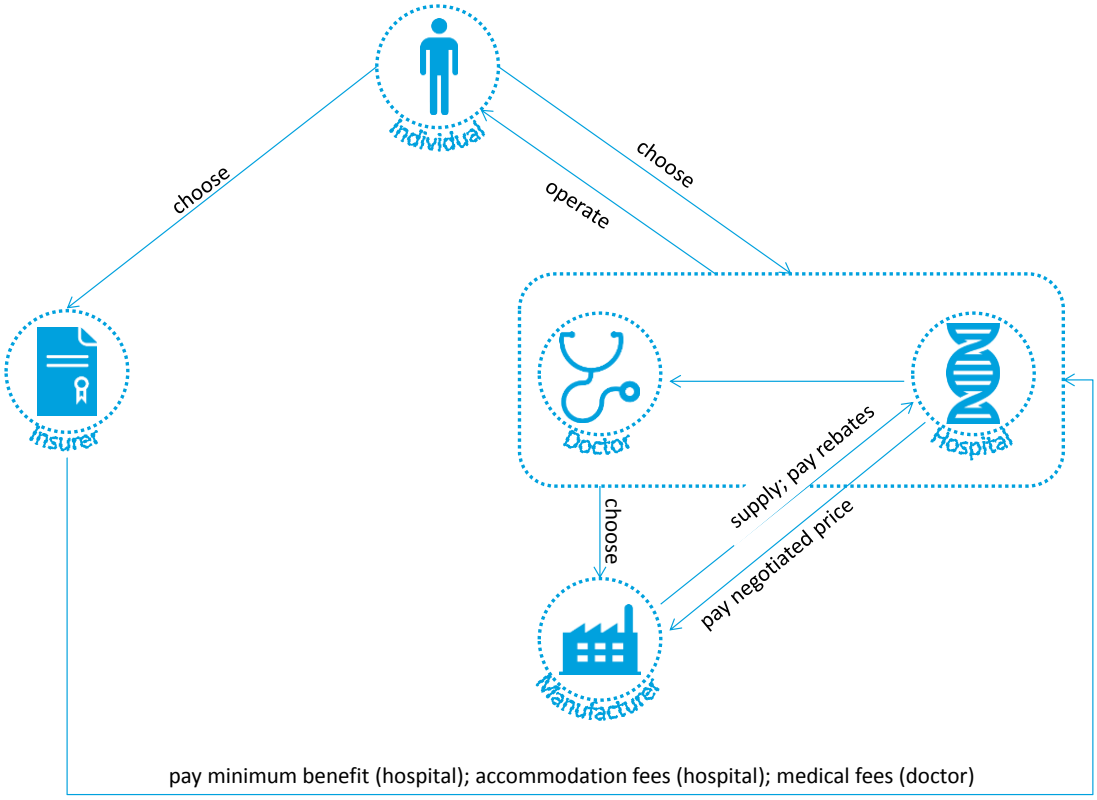
If the market consists of goods which are identical in all ways – including features, methods of use and marketing – then they are considered perfectly substitutable. As such, consumers will choose the cheapest product, since it provides the same benefit at a lower cost.

In practice, goods are almost never *exactly* the same. However, where there are only minor differences between products (for example, two products which are technically identical but are marketed under different brands), the same principle applies. Some individuals might have specific preferences which mean that they will prefer the more expensive product. Overall, demand should largely flow to the product which is most cost-effective.

This market structure will also encourage innovation. Firms will seek to increase their profits by either producing products in a more cost-effective manner, or by making products which consumers find more valuable. As such, the technical capabilities of the goods continue to improve, while prices decrease.

The market for prostheses in Australia does not have this structure. As detailed in Chapter 2, it is complicated by the involvement of several different players. Rather than a standard interaction between a buyer and a seller, hospitals and/or doctors purchase prostheses from suppliers on behalf of individuals. In turn, hospitals are paid the minimum benefit, as listed on the Prostheses List, by an individual's insurer. The insurer is paid premiums by the individual who receives the service. This process is illustrated in Figure 3.2.

Figure 3.2: Prosthesis procurement process



Source: DAE

The interactions between surgeons and hospitals in relation to prostheses procurement can vary on a case-by-case basis. Private hospitals compete to attract surgeons to their facilities, while surgeons seek conveniently located hospitals which have state-of-the-art facilities. Where surgeons have greater bargaining power, they are likely to have a greater influence over choice of prostheses.

Each of the players in this market faces different incentives. Rational participants will always act to maximise their own best interests. The factors which motivate the participants are shown below.

Table 3.1: Incentives of participants in the prostheses market(s)

	• Best possible care • Lowest premiums • Risk mitigation
	• Margin • Membership • Clinical cost effectiveness (including limiting risk of revisions)
	• Best possible care • Reputation/risk mitigation • Volume
	• Margin • Occupancy and throughput • Reputation/risk mitigation
	• Profit • Reputation/risk mitigation

Source: DAE

These differing incentives mean that agency problems arise – in particular between doctors/hospitals ('agents') and insurers ('principals'). Doctors/hospitals are effectively responsible for purchasing prostheses on behalf of insurers. However, insurers are unable to effectively monitor the actual cost of the prostheses (as charged to the doctor). Further, insurers do not have the expertise or legal ability to mandate which prostheses are chosen in what circumstances.

This lack of transparency and enforcement mechanisms means that surgeons and hospitals may have little regard to the interests of the insurers in purchasing prostheses on their behalf. Indeed, this market highlights the nature of principal-agent problems – even if an insurer knew that a doctor was making a self-motivated decision in purchasing an unnecessarily expensive prosthesis, they would still have no ability to do anything about it. Insurers have greater focus on clinical cost effectiveness. Surgeons and/or hospitals, on the other hand, will have a more direct focus on care (and muted regocnition of clinical cost effectiveness).

Consider a hypothetical example. A doctor has a choice between two products in the same group – Product X and Product Y. They have the same level of clinical effectiveness and serve the same purpose. Both have a minimum benefit amount of $500.

The manufacturers of Product X offer the hospital a rebate of $100, while the manufacturers of Product Y offer an up-front discount of $150. However, these are provided as part of varying contractual arrangements, and it takes the hospital some time to determine which product offers better value.

Given that the two products are substitutable, the hospital seeks to incentivise doctor choice of Product Y, as it offers a higher margin.

When billing the patient's insurer, the hospital lists the prosthesis. It charges the full minimum benefit amount, as required by the Regulations, of $500. The hospital captures the $150 discount as a margin.

The insurer is unable to determine that the hospital has only paid a net price of $350, and unable to react to this higher charge or negotiate lower charges in future.

Doctors and hospitals in the private system thus choose prostheses based on the incentives outlined in Table 3.1, namely to provide the best possible care for their patients and enhance their reputation. This is desirable. However, they have little incentive to be mindful of the cost to insurers (i.e. the minimum benefit) of the devices that they use. This is summarised by the Productivity Commission (2005), which explains that

> *"Without any gap payable for prostheses by insured patients, there is little incentive to select less expensive items. Indeed, for both the individual and his or her doctor, there is an incentive to select the best prosthesis available, without much regard for its cost."*

Minimum benefit rules mean that the hospital can be assured of receiving a given payment from insurers. Combined, these two factors mean that surgeons and hospitals may choose prostheses which do not have the highest level of clinical cost effectiveness. Since surgeons are fully compensated for the cost of prostheses they choose, they may also be less willing to change to more cost-effective prostheses if there are learning costs associated with using them.

Consider a hypothetical example. A doctor has a choice of two products for an elective surgery which achieve the same clinical purpose – Product A and Product B. If the product fails, the individual will need to undergo another surgery.

- Product A has a minimum benefit amount of $1000, and a success rate of 98.9%
- Product B has a minimum benefit amount of $100, and a success rate of 98.8%

The most efficient choice would be Product B, since it is substantially cheaper and only marginally less successful. However, the doctor does not care about the price. Money is not an object, since he knows the insurer will pay the minimum benefit and neither he nor his patient will be out of pocket for this. As such, he orders Product A, since it is more likely to be successful (thus improving patient outcomes and his or her own reputation)

This highlights the fact that the system has introduced examples of widely different prices for products which are clinically very similar. Prices are slow to adjust because of the inflexibility of the system.

These conflicting incentives are further exacerbated by volume rebates and other discounting arrangements negotiated between hospitals and suppliers. From advice provided by Jones Day, Deloitte Access Economics understands that hospitals are able to separately negotiate prostheses prices with suppliers. Under the current regulatory framework, insurers are not able to negotiate prostheses prices with suppliers.

These prices negotiated by hospitals ('actual price') can be significantly lower than those on the Prostheses List ('list price'), with manufacturers offering scale discounts and rebates. It is not clear whether these are different to prices that insurers would negotiate with suppliers, given the opportunity to do so. Hospitals are not required to disclose actual prices to insurers. Regardless, insurers are legally obliged to pay the list price, irrespective of actual price. As such, hospitals can capture the difference between list price and actual price as margin.

In contrast, in an unregulated market, manufacturers compete on price and features to win market share with hospitals. Hospitals, in turn, would compete between themselves to increase their market share or gain preferred status with insurers. This competition would take place on the basis of price as well as service. Ultimately, this would bid down the cost of prostheses to insurers. Hospitals would have an incentive to pass on a proportion of their cost savings to insurers.

This can be compared with the current market, where the actual price of prostheses is not observed by the insurer, and there is the potential to improve margins, as noted above. This provides an additional incentive for surgeons and hospitals which may conflict with the interests of insurers.

Returning to the hypothetical example of the doctor choosing between Product A and Product B. Further to the above, each offers actual prices which differ from list prices, as below.

- Product A has a minimum benefit amount of $1000, but only costs $70 to make. Manufacturer A offers a scale discount to the doctor, so that the actual price of product A will be $500
- Product B has a minimum benefit amount of $100, and costs $60 to make. Manufacturer B offers a year-end rebate based on volume to the doctor, so that the actual price of product B will be $80.

The doctor or hospital will capture the difference between the list price and the actual price. For Product A, this will be $500 ($1000-$500). For Product B, this will be $20 ($100-$80).

Knowing that Product A provides marginally better clinical effectiveness and higher profitability, the hospital incentivises doctor choice of Product A.

The two examples above illustrate how the current regulations and market structure can affect efficiency in the market by skewing decision making and incentives:

- **Patients** may be uncertain as to whether profit motives are affecting surgeons' choice of prostheses. They may also face higher insurance premiums than necessary, as potential cost savings in prostheses procurement are not passed on to insurers.
- **Insurers** have limited control over costs. Minimum benefits mean that prostheses costs are capped. However, they also limit the extent to which insurers can capture additional value which comes from supplier discounts or volume rebates associated with group buying.
- **Doctors and hospitals** face muted price signals. They focus on providing the best possible care, but have limited incentive to consider cost effectiveness when selecting prostheses. However, once a given prosthesis has been selected, they negotiate with manufacturers to secure the best possible price.
- **Manufacturers** may find it difficult to attract market share based on price leadership alone. Doctors and hospitals will be more likely to react to product innovation (including marketing and features) than price competition.

A detailed theoretical model of the decision-making process for doctors and hospitals is outlined in Appendix A below. This model shows that only if certain conditions hold will the most cost-effective prosthesis be chosen by health care providers.

3.2.1 Impact on premiums

These impediments to efficiency have a flow-on effect. Doctors and hospitals choose the most effective or familiar device, rather than the most clinically cost-efficient one. This is compounded by the gap between actual price and list price. Doctors and hospitals are not required – or able – to directly pass any negotiated savings on to health insurers. As such, by paying the list price, insurers may be paying more for prostheses than is necessary.

These costs are passed on to consumers through higher than necessary premiums. Consumer demand for health insurance, and thus the level of membership, decline as premiums increase..

3.2.2 Impact on choice

As noted previously, the prostheses market has natural characteristics that limit the extent of consumer choice. Consumers are not well equipped to assess the efficacy and appropriateness of competing products. They will rely on surgeons to make these choices on their behalf. This relationship will persist regardless of the regulatory framework.

Consumers are able to make two key choices through the process, as illustrated through Figure 3.2. In the first instance, a consumer makes a choice of insurer. Later, they can choose their doctor/hospital.

The current regulatory framework may limit the choices of insurance products available to consumers. All insurers must pay minimum benefits for any product in any category on the prostheses list. As noted above, this can lead to higher than necessary prices. Some consumers may in fact prefer to pay lower premiums but, for example, only have access to the most cost-efficient prosthesis in a given class. However, this choice is not available under the current regulatory arrangements.

3.2.3 Impact on innovation

Innovation in the market can be conducted by two players – insurers and manufacturers.

The prostheses regulations limit the ability of insurers to innovate. The existing framework means that insurers are legally obliged to pay the minimum benefit for all prostheses. They are not able to alter their offerings or alter prices (for example through co-payments). Insurers may be able to overcome these barriers somewhat by altering the services bundled with the prostheses themselves. However, the capacity to create innovative products directly relating to prostheses is limited.

For manufacturers, the regulatory regime generally encourages innovation. Products which can prove that they differ significantly in terms of form, function or effectiveness can be moved to a different classification. If a product is in a class ‘all of its own’, it may be able to secure greater market share and/or higher minimum benefit levels. However, the effect on incremental product innovation is not clear.

However, it is important to note that prostheses are researched and manufactured globally, as well as locally. The level of innovation in prostheses overall is not likely to be significantly affected by Australian regulations.

The Therapeutic Goods Administration (TGA) and PLAC process that manufacturers must undertake before their products are listed in the first instance is rigorous and time-consuming. However, this is designed to ensure that all products are of a high quality and do not create adverse effects for patients.

3.2.4 Impact on long-term sustainability of the insurance industry

The regulatory framework and minimum benefit regime appear to have contributed to capping the rate of growth in prostheses costs over time as compared to the immediately prior regulatory framework. It has helped to ensure that a wide range of products is available at costs that are stable with contained growth. This improves stability by ensuring that costs to insurers – and hence premiums – grow at a sustainable rate.

However, it may be possible to further contain growth in insurance premiums (to the extent that these are driven by prostheses prices). Low transaction costs and perfect information are bastions of perfectly competitive markets. These assumptions do not hold true in markets for prostheses. While the ideal of perfect competition is unobtainable in prostheses, the current system could be improved in order to move closer to this goal.

As noted above, list prices may be higher than actual prices, and the prostheses chosen are not necessarily the most cost-effective ones. If insurers were able to capture some of these potential savings, the long-term sustainability of private health insurance could be improved.

3.3 The market mechanism and the market for health care products

The market mechanism is the process by which goods and services are allocated in an economy. Where there is no government intervention in a market, price adjusts to equate the quantity of a particular good or service suppliers are willing to supply at that price with the quantity of a particular good or service consumers are willing to buy.

Economic theory has shown that under certain assumptions, the market mechanism will lead to an efficient quantity of goods and services being exchanged.[1] However, in many markets these assumptions may not hold which may lead to too many or two few goods and services being produced relative to the efficient level. For example, if a prosthesis had an unknown long-term side effect, this may lead to too many prostheses being produced relative to the socially efficient amount. Moreover, while the market mechanism may lead to an efficient outcome, that outcome may not always be regarded as equitable.[2]

Hence, there are a number of public policy considerations which may lead a government to intervene in a market(s). In particular, there are two key public policy considerations which potentially arise in the market for supplying prostheses to health care providers where these are covered by health insurance.

Product quality and safety considerations

If consumers or health care providers have imperfect information about the quality and safety of prostheses or the value of innovations provided by new products, regulatory processes can help address these information asymmetries. This is particularly the case if consumers are not sufficiently informed to assess the level of prostheses coverage provided by different levels of insurance coverage.

> Our assessment is that product quality and safety considerations are an important public policy consideration in this market.

Efficiency considerations

Insurers are required by legislation to provide choice and a benefit for any prosthesis which is on the Prostheses List. This means that there would be increased transaction costs to insurers if they were responsible for individually negotiating benefits for each prosthesis listed. The transactions costs associated with insurers negotiating prices for all prostheses may be too large or create entry barriers, which may justify the government setting minimum benefit levels for each class of prostheses.

[1] This is known as the First Theorem of Welfare Economics. It establishes that under certain conditions (such as individual rationality, perfect information, complete markets and the absence of externalities) a competitive market will lead to outcomes that are pareto efficient (that is an outcome in which no individual can be made better off without making someone else worse off).

[2] In theory, a government could address this issue by providing lump sum transfers between consumers without altering the market mechanism although government do not always choose to intervene in this way.

This was part of the rationale for the introduction of minimum benefits in 2005. Prior to this, insurers were required to negotiate and cover the cost of all prostheses used. However, in practice it is not clear how significant transaction costs are as private hospitals already negotiate prostheses prices with suppliers. Moreover, if minimum benefits are set too high, this may itself reduce allocative efficiency.

The nature of obligations placed on health insurers can also affect efficiency. For example, if health insurers are required to cover all prostheses (as was the case prior to 2005), this could lead to weaker incentives for other decision makers to choose more cost effective prostheses. While the introduction of minimum benefits is one way of addressing this, as noted at the time, it could also have been achieved through deregulating the types of prostheses insurers were required to cover.

Our assessment is that efficiency considerations are potentially important in this case. However, the extent to which this justifies government intervention will depend on the circumstances. If insurers are given flexibility as to the type and range of prostheses they cover, there is less of a justification for government intervention to promote cost-effectiveness or reduce transaction costs. However, if insurers are required to cover a specific range of prostheses there is a greater justification for governments to consider intervening to reduce transaction costs or promote cost-effectiveness.

4 Alternative regulatory frameworks

4.1 What might an alternative regulatory framework look like?

Economic principles can be used to help guide decision making under the current regulatory framework.

4.1.1 Reform options

This section briefly outlines what an alternative regulatory framework which sought to enhance the efficiency of the prostheses listing process might involve. The purpose of this section is not to set out the precise details of what an alternative regulatory framework should include, which is beyond the scope of this report, but to highlight some of the features that could help improve the efficiency of the prostheses listing process.

The analysis in this report has illustrated that the two main issues with the current regulatory framework are that:

1. Health care providers have limited incentives to choose prostheses which are the most cost effective for a given operation.
2. Minimum benefits are in many cases set at levels that are significantly higher than the price at which the lowest cost supplier in each benefit category is able to supply prostheses to private hospitals.

A range of policy responses could be given further consideration as a means of address to these issues. These should be considered as complements, rather than substitutes. It should be noted that any regulatory system will impose transaction, regulatory and compliance costs. These should be considered when examining policy options. Some potential options and specific considerations are set out below:

- The first option would be to introduce a disclosure regime, similar to that introduced in the Pharmaceutical Benefits Scheme. Under this model, hospitals would be required to disclose their actual (net) prices paid for prostheses to PLAC. If disclosure was made to PLAC, then information on actual (net) prices paid could be used to inform the minimum benefit setting process. This would help to ensure that PLAC set minimum benefits which were more closely aligned with actual prices paid.

  It is important to note that most prostheses manufacturers negotiate bundled contracts, which cover a variety of products (some of which may not be covered by the Prostheses List). Discounts or rebates are then given based on overall volume, spend, or other factors. For a disclosure regime to operate successfully, disaggregated net prices must be provided. Further, this regime may increase the burden on regulators, and increase compliance burdens for manufacturers.
- Secondly, PLAC could broaden the information sources it uses to inform the process of minimum benefit setting. Specifically, this could involve benchmarking prices against those paid in the public hospital system, or prices in comparable jurisdictions

overseas. Another potential benchmark could be any public standing offers for prostheses in a class, as issued by manufacturers.

Designing appropriate benchmarks – and sourcing the data to inform them – could be complicated by factors such as lack of choice (in the public system), exchange rate movements and market competitor strategies (in other jurisdictions). However, it could be done as a selective exercise for certain groups. Information gaps could be filled by encouraging proponents to bring forward information to help fill any significant gaps which emerge.

- Another option for reform could be allowing insurers to choose which prostheses to offer. Under this model, insurers could offer multiple products with varying levels of choice in prostheses. To ensure consumer protection, regulation could require that all products which advertise prostheses cover must provide at least one product in each group, as set by the PLAC. Individuals who choose products which were more expensive than the products covered by their fund would be required to pay the excess out of pocket.

  This approach may confuse consumers, who may find it more difficult to identify and purchase a health insurance product which is appropriate to their needs. It may also affect the level of consumer choice offered through PHI products.

- A final option would be to reconsider the scope of the Regulations and what items are included in the Prostheses List and Rules. For example, items in classes which are fairly competitive that can be substituted with non-listed items (such as sutures) could be excluded.

  In practice, it may be difficult to determine which items should be excluded, and which items should be listed.

4.1.2 Setting the minimum benefit

Under the current regulatory framework prostheses that perform the same clinical function with similar clinical effectiveness are to be listed in the same benefit category. Within a benefit category, if a range of products have the same or similar levels of clinical effectiveness (namely rival products are essentially homogenous), economic principles imply that suppliers should compete on the basis of price. Hence, prostheses should be sourced from the supplier in each benefit category that is able to supply it at the lowest price.

In a letter from the Medical Benefits Division (Bartlett, 2013), PLAC explains that "the methodology used to determine appropriate group benefits fixed the benefit price to a point where 25% of a group's utilisation had a listed benefit at or below that point". In a number of cases, this would imply setting the minimum benefit at a level above the listed benefit for the lowest cost supplier unless the lowest cost supplier had a market share that was greater than 25%.

In principle, setting the minimum benefit above the price at which the lowest cost provider is willing to supply would not necessarily affect the degree of price competition between suppliers in the market to supply products to health care providers, as they receive supplied prices rather than the minimum benefit. However, if the minimum benefit is greater than the lowest supplied price, this means that insurers are required to pay more than they otherwise would unless private hospitals chose to pass on any difference in full through

cross-subsidising other services paid for by private health insurers.[3] This, in turn, affects the cost of supplying health insurance and reduces demand for health insurance at the margin. Thus, once the impact on other markets is considered, minimum benefits should be set to match the price that would be charged by the lowest cost supplier.

The assessment of what price suppliers are willing to supply a product should be based on the actual prices charged by suppliers to health care providers, taking into account any rebates.[4] The level of the minimum benefit would need to be recalculated regularly, probably at least annually, to account for changing market conditions and fluctuations in exchange rates.

In practice, contracting processes may impede the ability of regulators to discern these actual prices. While minimum benefits are determined and set on a product-by-product basis, advice provided by Jones Day suggests that manufacturers tend to negotiate contracts and pricing with hospitals at a more aggregated level (for example, for all prostheses and supplies that may be purchased over the course of a given period, rather than by line-item). As such, information on actual price by line item may be difficult to ascertain. This also has the effect of muting hospital incentives to react to headline prices, as discussed previously.

While economic principles suggest that the minimum benefit should be equal to the lowest price at which a supplier is willing to supply a prostheses, it should be noted that in some cases this may not apply. These include situations such as where the lowest cost supplier is not able to supply the whole market.

Whether these sorts of considerations apply will depend on the particular benefit category and the nature of the listed prosthesis. However, applying a 25th percentile rule across the board is unlikely to be appropriate for all benefit categories.

Data and methodologies to be used in establishing groups and minimum benefit levels

The HTA Review concluded that classification of prostheses into different benefit categories should be based on assessments of clinical effectiveness so that products with higher levels of clinical effectiveness should be placed in separate categories. Assessments of relative cost effectiveness across classes would need to be based on clinical evidence and assessments by those with expertise in assessing relative cost effectiveness, with appropriate input from health economists. A number of health economists are currently members of PLAC.

The data used to establish the minimum benefit should be based on the average prices at which products are supplied to hospitals or health care providers. In practice, supplied prices may differ across suppliers, although the average should provide a reasonable proxy for the purpose of calculating minimum benefit levels. The supplied price should include any transport costs in delivering the product to health care providers.

[3] Cross-subsidisation in itself may lead to poorer assessment of risk by insurers which may have second order effects on the private health insurance market.

[4] In cases where the lowest priced supplier does not have sufficient scale to supply the market, it may be necessary to select the lowest price at which the whole market could be theoretically supplied for the minimum benefit. It is not clear how many benefit categories this issue might affect in practice.

4.1.3 Classifying prostheses into benefit categories

Based on the recommendations of the HTA Review, where a supplier is able to establish that their product has a higher level of clinical effectiveness than other products with the same clinical function, then that product should be listed in a separate benefit category.

Whether a product should be placed in a separate benefit category as a result of a slightly higher level of clinical effectiveness or ease of use is inevitably a question of degree that will depend on the medical role played by the prostheses and the assessed improvement in clinical effectiveness. Assessment of which categories a product should fall into would need to be supported by appropriate scientific or clinical evidence.

The minimum benefit for prostheses which are in a separate benefit category should be based on relative cost effectiveness in relation to other benefit categories.

However, if suppliers are currently supplying the prostheses at a price lower than the level of minimum benefit which would be consistent with relative cost effectiveness, the minimum benefit should be set at the price at which suppliers are currently supplying the prosthesis. In this case, allowing suppliers to instead charge the higher minimum benefit would not lead to less cost effective prostheses being chosen, but would lead to greater outlays for health insurers which would in turn affect the cost for private health insurance.

Particular grouping and minimum benefit that should be adopted in the case of clip appliers

The evidence provided to DAE by Jones Day indicates that the clip appliers in Applied Medical's benefit category have an identical or very similar level of clinical effectiveness and that any differences in ease of use were minor. Our conclusion below is based on this information and evidence.

Based on the principles outlined above, this suggests that these products should be placed in the same benefit category, as they are currently. The minimum benefit should be based on the lowest price at which a supplier is willing to supply the market.

Our understanding is that the current minimum benefit level, set at $412, does not reflect the lowest price at which a supplier is willing to supply the market. Suppliers of clip appliers will have different prices at which they are willing to supply the market. However, as noted above, the current principle for setting minimum benefits requires that it be set at a point such that 25% of supplied products were sold at a lower price.

Evidence provided by Jones Day suggests that 25% of supplied products had a lower price than $145, based on 2011-12 data from suppliers. As such, following existing regulatory principles, this should be set as the minimum benefit.

As noted above, a more effective principle would be to set the minimum benefit as the lowest price at which a single manufacturer was able and willing to supply the entire Australian market. This would be lower than $145. According to advice from Jones Day, Applied Medical currently supplies their product at a net price of $99 and is in a position to supply the whole Australian market.

It should be noted that one product by CK Surgitech Pty Ltd is listed with a minimum benefit of $80, although it is not clear if this product could be supplied to the entire market.

References

Bartlett (2013). Letter "Group Benefit Change -3.8.3.3 Clips with Disposable Applier, Endoscopic suffix". 18 September.

Department of Health and Ageing (2009). "Review of Health Technology Assessment in Australia" (HTA Review). Commonwealth of Australia.

Doyle et al (2007). "Review of the Prostheses Listing Arrangements"

Private Health Insurance Administration Council (2012). "Competition in the Australian Private Health Insurance Market", Premiums and Competition Unit Discussion Paper 1.

Productivity Commission (2009). "Public and Private Hospitals".

Productivity Commission (2005). "Impacts of Advances in Medical Technology in Australia".

Medical Technology Association of Australia (2013). "Medical Technology: Key facts and figures 2013".

Appendix A

An economic model of the choice of prostheses by health care providers

This model examines the conditions under which a health care provider will choose a given prosthesis under the current regulatory framework.

Model set-up

The model assumes that there are two prostheses in the market. Prostheses 1 is a low cost prostheses, while prostheses 2 is a higher cost prostheses.[5] It is assumed that both prostheses are supplied by manufacturers to hospitals at a price that is equal to or less than their respective minimum benefits. It is also initial assumed that the minimum benefit for prostheses 1 is lower than that for prostheses 2.

These assumptions are set out below:

$$p_{1<} \quad p_{2<}$$
$$B_{1<} \quad B_{2<}$$

$$p_1 \leq B_1, p_2 \leq B_{2<}$$

Where $p_{1<}$ and $p_{2<}$ are the prices of prostheses 1 and 2 respectively and $B_{1<}$ and $B_{2<}$ are the minimum benefits associated with prostheses 1 and 2 respectively.

The effectiveness of each prostheses is represented by $e_{1<}$ and e_2. It is assumed that there exists a function, $M(e)$, that is able to express the improvement in patient well-being or utility associated with a given level of effectiveness in monetary terms. This function is assumed to be increasing in effectiveness but strictly concave such that: $\frac{dM<}{de<} > 0, \frac{d^2M<}{de^2}$.

The relative cost-effectiveness of both products is represented by the average improvement in patient well-being per unit cost of a prostheses. This is represented by:

$$\frac{M(e)<}{p_{1<}}$$

Finally, a health care provider's reputation is assumed to be affected by the effectiveness of the prostheses they use. This assumption is adopted because patients are unlikely to be able to assess the extent to which the outcome of surgery was attributable to either the health provider's skill, the quality of the facility or the effectiveness of the prostheses used. Thus, where a less effective prosthesis is chosen by a health care provider, this is likely to have an adverse effect on the reputation of a particular health care providers (both

[5] The model can be extended to consider the case where there are more than two prostheses in the market but the analysis focuses on two products here for reasons of analytical simplicity.

hospitals and surgeons) in subsequent periods. In present value terms, the reputation effect of using a given prostheses is represented by:

$$\frac{R(e)<}{1-r<}$$

Where r is the intertemporal discount rate. $R(e)$ is increasing in effectiveness.

Case 1: $e_{1<}$ $e_{2<}$

In this case, the lower priced prosthesis (product 1) has a lower level of effectiveness. Health care providers will choose the prosthesis that maximises their profits in present value terms. The payoff associated with choosing prostheses 1 is represented by:

$$\pi_{1<} \quad (B_1 - p_1)q + qR(e_1)/(1-r)< \qquad (1)$$

$$\pi_{2<} \quad (B_2 - p_2)q + qR(e_2)/(1-r)< \qquad (2)$$

Rearranging equations (1) and (2) implies that a health care provider will choose product 1 whenever:

$$(<_{1<} - p_1) - (<_{2<} - p_2) > \frac{R(e_2)<}{(1-r)<} - \frac{R(e_1)<}{(1-r)<} \qquad (3)$$

That is, for a health care provider to choose product 1, the margin between the minimum benefit and price of product 1 much be sufficiently greater than the corresponding margin for product 2 to outweigh the adverse reputation effect of choosing product 1 with a lower effectiveness. This adverse reputation effect is shown on the right hand side of equation 3.

Conversely, a health care provider would always choose product 2 if the margin between its minimum benefit and price was equal to the corresponding margin for product 1. A health care provider would also choose product 2 in cases where the margin between its minimum benefit and price is smaller than product 1 but the difference between these two margins was less than the adverse reputation effect associated with choosing prostheses 1.

Relative cost effectiveness

The most cost effective prosthesis will be prostheses 1(2) where $\frac{M(e_1)<}{p_{1<}} > \frac{M(e_2)<}{p_{2<}}$. However, since cost effectiveness does not affect the decision of which prosthesis to use in equation 3, the choice of prosthesis will not necessarily be the most cost effective one.

For example, if prostheses 1 is more cost effective than prostheses 2 it will only be chosen if equation 3 holds, which depends solely on the relative margin between the minimum benefit and price for each of the prostheses and differences in effectiveness.

Case 2: $e_{1<}$ $e_{2<}$

In this case, both prostheses are equally effective and there is thus no adverse reputation effect associated with choosing prosthesis 1. Prostheses 1 will be chosen whenever:

$$(<_1 - p_1) > (<_2 - p_2)< \qquad (4)$$

This implies that product 1 will only be chosen when the margin between its minimum benefit and price exceeds that of product 2.

However, cost effectiveness would imply that product 1 should always be chosen as $M(e_1) < M(e_2)$ and the price of prostheses 1 is lower. Similarly, choosing product 1 would be consistent with improving efficiency in both the primary market for supplying prostheses to private hospitals and related markets.

In the primary market, efficiency would require the cheaper product (product 1) to be purchased given that both prostheses are equally effective. Similarly, since the minimum benefit attributable to product 1 is lower, the choice of product 1 would reduce the benefits payable by private health insurers and provide them greater scope to attract additional customers by lowering premiums.

Case 3: $B_{1<} \quad B_{2<}$

In this case both products have the same minimum benefit, despite differences in their supplied prices. Rearranging equation (3) implies that prostheses 1 would be chosen whenever:

$$p_2 - p_1 > \frac{R(e_2)<}{(1-r)<} - \frac{R(e_1)}{(1-r)<} \qquad (5)$$

That is, product 1 will be chosen where the difference between its price and that of product 2 exceeds the adverse reputation effect from using the less effective product. The adverse reputation effect is indicated by the right hand side of equation 5.

Appendix B: Terms of Reference

General Framework For Analysis:

1. *Please explain the prevailing state of economic thinking with respect to the following:*

   (a) *What is the "market mechanism" and what are the (dis)advantages of its use in determining the prices and quantities at which transactions should generally occur in any given industry in the economy?*

   (b) *What kinds of public policy considerations might arise in the context of the supply of medical products to health service providers where these are covered by health insurance might it be appropriate for regulation to supplement or replace the market mechanism?*

   (c) *How does the study of economics categories these public policy considerations? Are these considerations "efficiency considerations", "equity considerations" or other kinds of considerations? What do these categorisations mean and what role can the study of economics play in assisting to achieve these public policy aims?*

Markets:

Before turning to the specifics of the regulations that can or do apply:

2. *Identify the markets in which prostheses devices, medical services and insurance are provided.*

3. *Describe the nature of the existing and potential competition that you would expect to arise in these industries. Where relevant please consider the structure and performance of the markets supplying the same or similar products to the public system in Australia or to public or private systems in other countries.*

Current Regulatory Decisions Concerning Regulated Minimum Benefits:

4. *Please identify the most significant economic effects of the current regulatory decisions (ie the February Rules) with respect to the prostheses traded in the markets relevant to our client's products. This consideration should include the way the products are grouped and the minimum benefit levels set.*

   In your answer, please include a consideration:

   (a) *Of the incentives for different industry participants throughout the production chain.*

(b) With respect to selling individual units of product and more broadly in terms of all the key commercial terms in a relationship between the parties (including discounts or rebates for volume purchases or purchases of a range of different products).

(c) The net costs and benefits for individuals as well as the aggregate economy wide effects from a qualitative and, where possible, quantitative viewpoint.

5. To the extent that the study of economics can provide an answer to the following questions, please provide your opinions:

(a) Do the February Rules restrict competition?

[Reference: Competition Principles Agreement of 11 April 1995 (as amended 13 April 2007) art 5]

(b) Do the February Rules encourage people to have private health insurance, make private insurance competitive and attractive to consumers, and/or tend to promote consumer choice and innovation in healthcare?

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) p 6 [11]; *Parliamentary Debates,* Senate, 26 February 2007, 89 (Nigel Scullion) (Second Reading Speech for the *Private Health Insurance Bill 2006* (Cth))]

(c) Are the February Rules conducive to an efficient and competitive private health insurance industry?

[Reference: *Private Health Insurance Act 2007* (Cth) s 264-5 (objectives of the Private Health Insurance Administration Council; Explanatory Memorandum to the *National Health Amendment (Prostheses) Bill 2004* (Cth) p 5]

(d) Are the February Rules an efficient regulatory framework?

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) pp 5, 15 and 21]

(e) Do the February Rules encourage the private health sector to deliver health services efficiently?

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) p 6]

(f) Do the February Rules promote the long term sustainability of the health insurance industry?

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) p 6]

(g) *Do the February Rules assist Australians to participate further in private health insurance, and/or enhance the value of private health insurance for the Australian community?*

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) p 6]

(h) *Do the February Rules reduce or increase the pressure on the level of private health insurance premiums?*

[Reference: *Parliamentary Debates*, House of Representatives, 7 December 2006, 7 (Tony Abbott) (Second Reading Speech for the *Private Health Insurance Bill 2006* (Cth)); Explanatory Memorandum to the *National Health Amendment (Prostheses) Bill 2004* (Cth) pp 4 and 5]

(i) *Are the February Rules likely to reduce the growth in prostheses benefits over time?*

[Reference: Explanatory Memorandum to the *National Health Amendment (Prostheses) Bill 2004* (Cth) p 5]

(j) *Are the February Rules likely to provide contributors with more choice in the provision of prostheses?*

[Reference: Explanatory Memorandum to the *National Health Amendment (Prostheses) Bill 2004* (Cth) p 5]

***Alternatives Under the Current Regulatory Framework**:*

6. *Within the confines of the existing regulatory framework of grouping prostheses and setting minimum benefit levels, what economic principles can guide the decision making?*

7 *What are the sources of data and methodologies best used for establishing groups and minimum benefit levels?*

8. *Does the economics suggest that a particular grouping should be adopted for our client's products? Does the economics suggest a particular minimum benefit level should apply?*

Appendix C: Index – responses to terms of reference

The section below presents brief responses to the terms of reference provided, and refers to relevant sections and page numbers. The responses listed in the section below are for brevity only, and as such are not intended to serve as a complete response. Given the complexity of issues discussed, the body of the report should be consulted for more robust responses and explanations.

General Framework For Analysis:

1. *Please explain the prevailing state of economic thinking with respect to the following:*

   (a) What is the "market mechanism" and what are the (dis)advantages of its use in determining the prices and quantities at which transactions should generally occur in any given industry in the economy?

In document, see
Section: 3.3
Pages: 17 19

Brief answer: The market mechanism is the process by which goods and services are allocated in an economy. Economic theory has shown that under certain assumptions, the market mechanism will lead to an efficient quantity of goods and services being exchanged. However, the market mechanism does not consider non-economic factors, such as equity. Efficient allocation results in better outcomes for consumers, as any changes in cost are passed through, and suppliers have incentives to innovate and introduce new products.

(b) What kinds of public policy considerations might arise in the context of the supply of medical products to health service providers where these are covered by health insurance might it be appropriate for regulation to supplement or replace the market mechanism?

In document, see

Section: 2.1.1

Pages: 3

Brief answer: In the market for prostheses, incentives are muted and there is a lack of transparency in pricing, resulting in market mechanisms not working effectively. Thus, there is the potential for regulation to improve the operation of the market. The original rationale for intervention in the provision of prostheses by the private health system was to ensure that individuals were provided with choice, high quality care and certainty of coverage. The policy rationale for establishing a minimum benefit was to provide a price cap so as to control growth in the cost of prostheses over time.

(c) *How does the study of economics categories these public policy considerations? Are these considerations "efficiency considerations", "equity considerations" or other kinds of considerations? What do these categorisations mean and what role can the study of economics play in assisting to achieve these public policy aims?*

In document, see

Section: 3.3

Pages: 17 19

Brief answer: The market for prostheses has underlying characteristics (including muted price signals and bundling behaviours) that impede efficiency. Thus, there are efficiency considerations. This can have a negative impact on consumer outcomes. As noted above, there is the potential for regulation to improve the overall operation of the market. However, there are questions about the feasibility of designing and implementing policies which do this effectively.

Markets:

Before turning to the specifics of the regulations that can or do apply:

2. *Identify the markets in which prostheses devices, medical services and insurance are provided.*

In document, see

Section: 3.1

Pages: 7 9

Brief answer: The relevant market(s) is the market(s) for supplying prostheses to private hospitals in Australia. Related markets include the market(s) for private health insurance in Australia and the market(s) for private hospital services in Australia.

3. *Describe the nature of the existing and potential competition that you would expect to arise in these industries. Where relevant please consider the structure and performance of the markets supplying the same or similar products to the public system in Australia or to public or private systems in other countries.*

In document, see

Section: 3.2

Pages: 9 14

Brief answer: Some of the key features of existing and potential competition in the relevant industries are described as follows.

Consumers purchase private health insurance products, which provide coverage against private health services, including the provision of prostheses. Deloitte Access Economics (2013) found that premium increases across funds increasingly concentrate around a narrow premium average, particularly among larger funds. This suggests that insurers compete for consumers primarily on the basis of product features (for example, marketing and waiting times for extras); premiums (prices) are regulated. Private patients are referred to surgeons, who may work in one or more hospital. Prostheses are procured from manufacturers by hospitals. Surgeons are primarily responsible for choice of prostheses, although this may be influenced by hospitals.

Insurers and hospitals negotiate contracts that cover a range of individual services and products that make up an episode of treatment. These contracts tend to cover all treatments undertaken over the contractual period. Prices are influenced by a number of factors. For episodes of treatment involving the use of listed prostheses,

hospitals bill insurers the minimum benefit amount, irrespective of the net price of the prostheses. There may be cross-subsidisation embedded in insurer-hospital contracts. The extent of this is not clear.

Hospitals negotiate bulk contracts with manufacturers of prostheses. These can cover a range of products, including ones which are not covered by the Prostheses List. Most manufacturers offer quantity-based discounts or rebates. These are generally not disclosed or applied at an individual item level.

In the process of this engagement, the scope of analysis expanded beyond the specific impacts of the February Rules to consider the effects of the current process of prostheses listing, grouping and pricing in the private health system more broadly. As such, questions relating to the February Rules have instead been answered more generally.

As noted above, the structure of the prostheses market results in some market distortions. Responses below consider this structure, and its impacts in relation to specific questions. It goes on to consider the extent to which regulation could be used to address these issues.

Current Regulatory Decisions Concerning Regulated Minimum Benefits:

4. *Please identify the most significant economic effects of the current regulatory decisions (ie the February Rules) with respect to the prostheses traded in the markets relevant to our client's products. This consideration should include the way the products are grouped and the minimum benefit levels set.*

In your answer, please include a consideration:

(a) Of the incentives for different industry participants throughout the production chain.

In document, see

Section: 3.2

Pages: 9 17

Brief answer: Individuals have incentives to secure the best possible care, and decrease risk of revisions. They also have a muted incentive to pay the lowest possible premiums (moral hazard means that those who do require surgery will not immediately be concerned about price to insurers).

Insurers have incentives to improve their margins, and ensure clinical cost effectiveness of prostheses (including by limited the risk that revisionary surgery is required).

Doctors and/or surgeons have incentives to give their clients the best possible care, and mitigate risks of adverse outcomes to customers as well as reputational risks. They also have an incentive to see as many patients as possible. The current

regulations mean that doctors and/or surgeons have muted incentives to be concerned about the price of prostheses that they purchase.

Hospitals have incentives to maximize their margins, whilst ensuring high quality in order to mitigate against risks and maintain reputation. Hospitals face muted price signals, as, under the current regulatory system, they are required to charge minimum benefits directly to insurers.

The incentive to maximize margins also means that hospitals may be mindful of discounts and/or rebates offered when choosing prostheses suppliers.

(b) With respect to selling individual units of product and more broadly in terms of all the key commercial terms in a relationship between the parties (including discounts or rebates for volume purchases or purchases of a range of different products).

In document, see

Section: 3.2

Pages: 10 14

Brief answer: Contracting arrangements in the current market structure revolve around the sale of bundled goods. These can include prostheses currently included on the Prostheses List as well as non-listed goods. Manufacturers then offer volume based discounts and/or rebates. These are not generally negotiated or disclosed on an individual line-item basis. Given this lack of transparency in pricing, the effect of the regulatory system on the relationship between hospitals and manufacturers is unclear.

According to advice provided by Jones Day, the degree of rebates and/or discounts is such that net prices are significantly different to minimum benefits. Given that rebates and/or discounts contribute to hospital margins, and hospitals are unable to un-package bundled prices, an inefficient volume of prostheses may be used, or hospitals may not be able to determine which prostheses are most cost effective.

(c) The net costs and benefits for individuals as well as the aggregate economy wide effects from a qualitative and, where possible, quantitative viewpoint.

In document, see

Section: 3.2

Pages: 9 17

Brief answer: Net costs and benefits for individuals as well as aggregate economy wide effects will depend on the degree of cross-subsidisation and competition along the value chain. Advice provided by Jones Day suggests that minimum

benefits are poorly calibrated to actual net prices in the market. All else being equal, this would imply that insurers are paying more than necessary for prostheses, which leads to higher premiums in the long run for consumers.

However, insurers may compensate for these margins accruing to hospitals by negotiating lower prices for other elements of treatment (for example, theatre fees or day costs). If this was the case, then there would less net impact on private health insurance premiums. As such, the net costs and benefits to individuals will be dependent on the degree of cross-subsidisation, and the extent of discrepancies between minimum benefit and net prices. Even if there is extensive cross-subsidisation, there would be negative impacts on efficiency, because price mechanisms are not accurately reflective of actual underlying cost, which cost lead to resources being allocated poorly.

5. *To the extent that the study of economics can provide an answer to the following questions, please provide your opinions:*

(a) Do the February Rules restrict competition?

[Reference: Competition Principles Agreement of 11 April 1995 (as amended 13 April 2007) art 5]

In document, see

Section: 3.2

Pages: 9 14

Brief answer: A lack of price transparency (through bundling) and some adverse incentives (particularly for hospitals) are underlying characteristics of the market which impact on the level of competition. The current regulatory framework prohibits insurers from competing to lower prices by negotiating lower prostheses prices with hospitals. The process of grouping prostheses into classes which have similar clinical effectiveness can limit inter-group price competition.

(b) *Do the February Rules encourage people to have private health insurance, make private insurance competitive and attractive to consumers, and/or tend to promote consumer choice and innovation in healthcare?*

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) p 6 [11]; *Parliamentary Debates,* Senate, 26 February 2007, 89 (Nigel Scullion) (Second Reading Speech for the *Private Health Insurance Bill 2006* (Cth))]

In document, see

Section: 3.2

Pages: 14 16

Brief answer: Depending on the level of cross-subsidization, the regulatory system could lead to higher prostheses prices and thus higher premiums, making private health insurance less attractive to consumers in the long run. However it improves surgeon/individual choice of prostheses by limiting affordability concerns for individuals. This makes health insurance more attractive to individuals. The net effect of these two factors on the attractiveness of private health insurance is not clear. Impacts on innovation in prostheses are likely to be marginal.

(c) *Are the February Rules conducive to an efficient and competitive private health insurance industry?*

[Reference: *Private Health Insurance Act 2007* (Cth) s 264-5 (objectives of the Private Health Insurance Administration Council; Explanatory Memorandum to the *National Health Amendment (Prostheses) Bill 2004* (Cth) p 5]

In document, see

Section: 3.2

Pages: 9 14

Brief answer: The current regulatory framework prohibits insurers from competing to lower prices by negotiating lower prostheses prices with hospitals. Bundling in hospital-manufacturer contracts distorts price signals. This could lead to an inefficient use and pricing of prostheses.

(d) Are the February Rules an efficient regulatory framework?

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) pp 5, 15 and 21]

In document, see

Section: 3.3

Pages: 17 19

Brief answer: The current system is intended to address inefficiencies created by the structure of the prostheses market. It appears to have contributed to capping the rate of growth in prostheses costs over time, as compared to the immediately prior regulatory framework. However, as identified through the report, the regulatory system has not addressed muted price signals and adverse incentives (particularly for hospitals). Further, it has prohibited insurers from competing to lower prices by negotiating lower prostheses prices with hospitals. It appears that there is scope for changes to the existing regulatory framework to improve efficiency.

(e) Do the February Rules encourage the private health sector to deliver health services efficiently?

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) p 6]

In document, see

Section: 3.2

Pages: 9 14

Brief answer: The current system appears to have had a role in capping growth in prostheses prices over recent years. However, it has also facilitated muted price signals that can impede efficiency. Other methods of delivering prostheses-related health services to private patients might be more efficient.

(f) *Do the February Rules promote the long term sustainability of the health insurance industry?*

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) p 6]

In document, see

Section: 3.2

Pages: 16

Brief answer: It is not possible with available evidence to determine what prostheses prices in the private health system would be if there was no regulatory framework in place. However, the current regulatory framework and minimum benefit regime appears to have contributed to capping the rate of growth in prostheses costs over time as compared to the immediately prior regulatory framework. This contributes to the long term sustainability of the health insurance industry.

However, it may be possible to further contain growth in insurance premiums (to the extent that these are driven by prostheses prices). Advice provided by Jones Day suggests that minimum benefits paid by insurers are higher than actual net prices paid. This difference may be recouped somewhat by negotiating lower prices for other services provided by the hospital. The degree of this cross-subsidization is unclear. In any case, cross-subsidisation will cause inefficiencies to arise, since prices do not reflect underlying costs, and as such services may be over- or under-utilized.

(g) *Do the February Rules assist Australians to participate further in private health insurance, and/or enhance the value of private health insurance for the Australian community?*

[Reference: Explanatory Memorandum to the *Private Health Insurance Bill 2006* (Cth) p 6]

In document, see

Section: 3.2

Pages: 14 15

Brief answer: The regulatory framework and minimum benefit regime appears to have contributed to capping the rate of growth in prostheses costs over time as compared to the immediately prior regulatory framework. This contributes to consumers receiving increased value from the health insurance industry. It improves surgeon/individual choice of prostheses by limiting affordability concerns for individuals . This makes health insurance more attractive to individuals.

However, depending on the level of cross-subsidization, the regulatory system could lead to higher prostheses prices and thus higher premiums, making private health insurance less attractive to consumers in the long run.

(h) Do the February Rules reduce or increase the pressure on the level of private health insurance premiums?

[Reference: *Parliamentary Debates*, House of Representatives, 7 December 2006, 7 (Tony Abbott) (Second Reading Speech for the *Private Health Insurance Bill 2006* (Cth)); Explanatory Memorandum to the *National Health Amendment (Prostheses) Bill 2004* (Cth) pp 4 and 5]

In document, see

Section: 3.2.1

Pages: 14

Brief answer: Since 2005, expenditure on prostheses per treatment episode has grown below the rate of inflation (Medical Technology Association of Australia 2013). While a number of factors (such as more efficient use of prostheses) may have contributed to this, it suggests that the reforms have played a role in limiting the rate of growth in prostheses prices. Given that prostheses are a significant component of costs to private health insurers, this may have played a role in reducing the pressure on the level of private health insurance premiums. Jones Day has advised that prostheses prices paid by insurers (through minimum benefits) are higher than the net prices paid by hospitals (although this may be recouped through lower prices for other components of patient care). This suggests that further regulatory reform would reduce the pressure on the level of private health insurance premiums.

(i) Are the February Rules likely to reduce the growth in prostheses benefits over time?

[Reference: Explanatory Memorandum to the *National Health Amendment (Prostheses) Bill 2004* (Cth) p 5]

In document, see

Section: 2.3

Pages: 4 6

Brief answer: Since 2005, expenditure on prostheses per treatment episode has grown below the rate of inflation (Medical Technology Association of Australia 2013). While a number of factors (such as more efficient use of prostheses) may have contributed to this, it suggests that the reforms have played a role in limiting the rate of growth in prostheses prices. Advice provided by Jones Day suggests that

once minimum benefit levels are set, they tend to be sticky and persist over time. New products without clinical equivalents have a high degree of influence over the minimum benefit for their new class. As such, it is not clear that the current system will continue to reduce the growth in prostheses benefits over time.

(j) Are the February Rules likely to provide contributors with more choice in the provision of prostheses?

[Reference: Explanatory Memorandum to the *National Health Amendment (Prostheses) Bill 2004* (Cth) p 5]

In document, see

Section: 3.2.2

Pages: 15

Brief answer: Consumers are not well equipped to assess competing prostheses. They will necessarily rely on surgeons to make these choices on their behalf. This relationship will persist regardless of the regulatory framework. However, it enables improves surgeon/individual choice of prostheses by limiting affordability concerns for individuals surgeon/individual choice of prostheses.

Alternatives Under the Current Regulatory Framework:

6. Within the confines of the existing regulatory framework of grouping prostheses and setting minimum benefit levels, what economic principles can guide the decision making?

In document, see

Section: 4.1

Pages: 20 24

Brief answer: In a simple and competitive market structure, consumers would act individually to choose products based on price signals and quality/value. The private health market for the provision of prostheses is complicated by a range of factors (information asymmetries, principal-agent problems etc) which make this unfeasible. However, regulatory frameworks should consider means to better align incentives and encourage competition in order to drive increased efficiency. This might include consideration of factors such as price transparency and facilitating competition by allowing insurers greater freedom in negotiations with hospitals (particularly in regards to prostheses prices).

7 What are the sources of data and methodologies best used for establishing groups and minimum benefit levels?

In document, see

Section: 4.1

Pages: 19 22

Brief answer: Minimum benefits should reflect actual prices in the market as much as possible, in order to encourage efficient use of prostheses. Additional data could be used to ensure that minimum benefit levels are as closely calibrated as possible. Data could include disclosure on net prices, standing public offers and benchmarking (both international and with the public system).

8. *Does the economics suggest that a particular grouping should be adopted for our client's products? Does the economics suggest a particular minimum benefit level should apply?*

In document, see

Section: 4.1.3

Pages: 22

Brief answer: Based on advice provided by Jones Day, these products are identical or very similar in clinical effectiveness and use. Under this advice, they should be placed in the same benefit category, as they are currently. In a perfectly competitive market, suppliers will compete on price, bidding prices down until a point where the prevailing price in the market is the lowest price at which a supplier is willing to sell. This is the efficient price. As such, the minimum benefit should be based on the lowest price at which a supplier is willing to supply the market. However, there may be cases where the lowest price supplier is unable to serve the whole market, but other suppliers are unwilling to sell at the same price. As such, the minimum benefit should be based on the lowest price at which a supplier is both willing and able to supply the entire market.

Appendix D: Qualifications and disclaimers

This report has been prepared solely for the purpose set out in Chapter 1 and does not seek to form an opinion as to any legal issues. This report should not be used for any other purpose without prior written consent from Deloitte. Neither \ Deloitte, its employees oragents accept any liability or responsibility for loss suffered by any party as a result of the circulation, publication, reproduction or other use of this report contrary to the provisions of this paragraph.

The statements and opinions contained in this report are given in good faith. However, inpreparing this report, we have considered the information set out in the references and inline throughout the document. We have not examined original documentation (unless otherwise stated). We have not been asked to, nor have we conducted an audit or otherwise verified the completeness and accuracy of the material made available to us. Accordingly, we do not accept any responsibility for any errors that result from reliance thereon.

The fees charged by Deloitte in this matter are based on time spent by partners and staffinvolved in the assignment at hourly rates prevailing at the time the work is undertaken. Payment of Deloitte's fees are not contingent on the outcome of this report.

We reserve the right to review and alter the conclusions reached in this report, should information that is relevant to my conclusions come to my attention after the date of this report.

Dr Ric Simes

Partner – Economics

Direct: +61 (0) 2 9322 7772
Email: rsimes@deloitte.com.au
Location: Sydney

Dr Ric Simes has extensive knowledge in public policy, governance, finance, econometrics, economic analysis and strategy. Ric has led numerous projects in the digital economy, financial services, climate change, energy, transport and water.

Background	Ric Simes has extensive knowledge in public policy, governance, finance, econometrics, economic analysis and strategy. He has held senior positions in the Commonwealth Treasury, academia, Prime Minister Keating's Office and the private sector before joining what is now, Deloitte Access Economics late in 2005. Ric has led numerous projects in the analysis of public policy, planning and regional development issues, financial services, climate change, energy, transport, water and the digital economy.
Skills & expertise	Demonstrated expertise in economic analysis and public policy. In depth understanding of the operation of the Australian economic and financial system that blends policy analysis and first hand capital market expertise. Capacity for representing interests of clients in their dealings with government and regulatory agencies at the most senior levels.
Professional and academic qualifications	Ph.D (Economics), University of Pennsylvania; M.Ec, Australian National University; B.Comm (Honours), UNSW. Director of Access Economics & Chief Strategist for Access Capital Advisers
Previous roles	Vice President, CRA International; Principal, NECG Head of Economic Team, ICAP (a major inter-dealer broker) Chief Economist and Executive Director, NM Rothschild (Aust) Ltd Senior Economic Adviser to the then Prime Minister of Australia, Paul Keating, throughout his period of Office. Areas of responsibilities included macroeconomic developments, budget policy, taxation, superannuation, industry policy, competition policy, land management and infrastructure Various senior positions in the Commonwealth Treasury both in

Australia and overseas (including the OECD)

Visiting Fellow at the Research School of Social Sciences at the Australian National University (1988)

Publications

Numerous publications on macroeconomics and applied econometrics as well as regular contributions to leading newspapers

Conferences and training courses

Regular addresses to conferences on public policy, financial markets and macroeconomics

Professional Experience

- **Director, Deloitte Access Economics and Access Economics**
  - Dr Simes has led numerous projects for financial institutions and government agencies. Dr Simes has provided advice on, *inter alia,* retail payment systems, prudential regulation, credit reporting, disclosure regulation, export of financial services, the mortgage market and financial derivatives
  - Telecommunications - the NBN and the allocation of spectrum for government and private sector clients
  - Digital - Impact of Digital technologies on the economy and social well-being
  - Indigenous Affairs - deep understanding of policy issues relevant to Indigenous Australians including native title regimes, land and resource management, social and economic development, capacity building and service delivery
  - Climate Change Policy - advice to government, industry and superannuation funds on the impact of climate change and climate change policy
  - Energy and Water – advice on policy and regulations to electricity and water utilities; advice on social economic impact of less water in the Murray Darling Basin
  - Trade & Industry – advice on major trends affecting the structure of industry in Australia; advice on policy related to innovation, research and development and, exports.
  - Strategic advice for superannuation funds on investments in infrastructure and other projects.
  - Intergovernmental Policy - Commissioned by the Council of Australian Governments (COAG) Reform Council (CRC) to assess 1) progress under the COAG reform agenda and 2) the effectiveness of the Intergovernmental Agreement on Federal Financial Relations (IGA) to drive reform.

Major clients served

Commonwealth and State Government Departments, Sydney Ports Corporation, Port of Brisbane, Google Australia, Australian Bankers Association, Regional Australia Institute, Genworth Financial

Limitation of our work

General use restriction

This report was prepared at the request of Applied Medical. This should not be relied upon by anyone else and we accept no duty of care to any other person or entity. The report has been prepared for the purpose of a submission by Applied Medical in informing regulatory and policy decisions. You should not refer to or use our name or the advice for any other purpose.

Contact us

Deloitte Access Economics
ACN: 149 633 116

Level 1
225 George St
Sydney NSW 2000
PO Box 6334
Kingston ACT 2604 Australia

Tel: +61 2 6175 2000
Fax: +61 2 6175 2001

www.deloitteaccesseconomics.com.au

Deloitte Access Economics is Australia's pre-eminent economics advisory practice and a member of Deloitte's global economics group. For more information, please visit our website www.deloitteaccesseconomics.com.au

About Deloitte

Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited, a UK private company limited by guarantee, and its network of member firms, each of which is a legally separate and independent entity. Please see www.deloitte.com/au/about for a detailed description of the legal structure of Deloitte Touche Tohmatsu Limited and its member firms.

Deloitte provides audit, tax, consulting, and financial advisory services to public and private clients spanning multiple industries. With a globally connected network of member firms in more than 150 countries, Deloitte brings world-class capabilities and deep local expertise to help clients succeed wherever they operate. Deloitte's approximately 200,000 professionals are committed to becoming the standard of excellence.

About Deloitte Australia

In Australia, the member firm is the Australian partnership of Deloitte Touche Tohmatsu. As one of Australia's leading professional services firms. Deloitte Touche Tohmatsu and its affiliates provide audit, tax, consulting, and financial advisory services through approximately 6,000 people across the country. Focused on the creation of value and growth, and known as an employer of choice for innovative human resources programs, we are dedicated to helping our clients and our people excel. For more information, please visit our web site at www.deloitte.com.au.