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SENATE INQUIRY INTO PRICE REGULATION ON THE PROSTHESES LIST

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A recent Senate Inquiry investigated the Prostheses List (PL) which has been an integral part of the private health care system since its introduction in 1985. The PL sets the price of various prostheses products available for private health insurance patients. In recent years however, the PL has come under scrutiny due to the inflated prices of prostheses, lack of transparency from the list’s creators and regulators, and increased premiums. This column critically analyses the recent Senate report, particularly as to whether it appropriately addressed the various concerns and issues raised in submissions and terms of reference of the inquiry and what ongoing role the PL should have in the Australian Healthcare System.

Keywords: Prostheses List; private health insurance; therapeutic goods administration

INTRODUCTION

On 13 October 2017 the Federal Minister for Health announced that the minimum benefits payable by private health insurers for devices on the Prostheses List (PL) would be reduced as of 1 February 2018. This decision arose after the report of a Senate Community Affairs References Committee into the PL.1 The PL is the list of surgically implanted prostheses, human tissue items and other medical devices that private health insurers must pay benefits for when they are provided to a patient with appropriate health insurance cover; they are provided as part of hospital treatment or hospital substitute treatment, and there is a Medicare benefit payable for the service. The list is aimed at private health insurers, prostheses device manufacturers and other sponsors. The PL has been an integral part of the private health care system since its introduction in 1985.2 The PL sets the minimum price of various prostheses products that private health insurance companies must cover for their duly insured patients.3 If the PL minimum benefit does not cover the cost of the prostheses to the hospital, then the patient has to pay all or part of the gap (the difference between the minimum benefit and the cost of the prostheses which will be decided by the hospital).

The Senate Inquiry arose because the PL has come under scrutiny due to the inflated prices hospitals are required to pay for prostheses relative to that private insurers are required to pay under the PL.4 This column will critically examine that Senate Committee’s PL report with an eye to exploring the true value

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1 Community Affairs References Committee, Parliament of Australia, Price Regulation Associated with the Prostheses List Framework (2017).

2 Community Affairs References Committee, Parliament of Australia, n 1, 4, [1.1]–[1.4].

3 Community Affairs References Committee, Parliament of Australia, n 1.


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and benefits of the PL and in doing so, attempt to determine its ongoing place in an Australian Healthcare
System where the principle of equity of access is viewed as a foundation of our social virtues, cohesion
and flourishing.

**WHAT IS THE PROSTHESES LIST?**

The PL is a list of prostheses products available to private health insurance patients. A prosthesis is
an artificial substitute or replacement body part attached or applied to the body to replace a missing
part. The types of prostheses on the PL include (but are not limited to): hip, knee and other joint
replacement devices; cardiac implantable electronic devices such as pacemakers and defibrillators;
cardiac stents; vascular stents and grafts; heart valves; and human tissue items such as whole bones and
bone fragments, corneas and heart valves. Devices such as external limb prosthetics, external breast
prostheses and implants used solely for cosmetic purposes are not on the PL. The PL includes more than
10,000 surgically implanted prostheses, human tissue items and other medical devices. It also shows the
minimum benefits that private health insurers must pay for each prosthesis.

The PL is regulated by the Australian Government and sets out minimum benefit levels to be paid
by insurers. The PL is primarily regulated by Div 72 of the *Private Health Insurance Act 2007* (Cth)
(*The Act*). The *Private Health Insurance (Prostheses) Rules* (*The Prostheses Rules*) are designed so that
private patients should occur no out-of-pocket expenses for prostheses devices. The PL was also designed
to give physicians the choice to select prostheses that are clinically appropriate for their patients. If a
patient is having surgery to implant or apply a prosthesis, then if that prosthesis is listed on the PL his or
her private health insurer must pay a benefit for it if that patient has the correct cover for the treatment.

*The Act* requires private health insurers must pay the amount as listed on the PL for prostheses and
*The Prostheses Rules* set out the listing criteria. The PL constitutes of three separate parts:
- Part A: surgically implantable devices;
- Part B: biological human tissue-based products, regulated by the Therapeutic Goods Administration;
- Part C: all other products that do not fit into the definition of Part A or B will be considered as
  prosthesis at the Minister’s discretion. At this stage, the Minister’s discretion is “limited to infusion
  pumps, implantable cardiac even recorders and cardiac home/remote monitoring systems.”

These parts are further divided into four different classifications: categories, subcategories, groups
and subgroups. Each group contains competing products with rebate figures applying for each product. In
a practical sense, the PL is governed by secretariat support in the form of the Prostheses List Advisory
Committee (PLAC), acting as representative for the Minister. Therefore the Australian Government
is responsible for the changes made to prostheses prices while the key stakeholders are involved in the
reimbursement process.

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5 Community Affairs References Committee, Parliament of Australia, n 1.
6 Community Affairs References Committee, Parliament of Australia, n 1.
7 Department of Health, Submission No 38 to Community Affairs References Committee, Parliament of Australia, *Price Regulation
   Associated with the Prostheses List Framework*, 17 February 2017, 3.
8 Community Affairs References Committee, Parliament of Australia, n 1, 4, [1.1]–[1.4].
9 Community Affairs References Committee, Parliament of Australia, n 1.
10 Community Affairs References Committee, Parliament of Australia, n 1, 4, [1.16].
11 Community Affairs References Committee, Parliament of Australia, n 1.
12 Community Affairs References Committee, Parliament of Australia, n 1.
13 Community Affairs References Committee, Parliament of Australia, n 1.
14 Community Affairs References Committee, Parliament of Australia, n 1.
15 Healthscope, Submission No 42 to Community Affairs References Committee, Parliament of Australia, *Price Regulation
   Associated with the Prostheses List Framework*, March 2017, 3.
Australia’s health care system is divided into public and private sectors with more than 13.5 million Australians having some form of private health insurance but all being covered by universal health coverage in the form of taxpayer-funded Medicare arrangements. This is a much cheaper and more efficient model than the fully privatised US health care system, though subject to incessant private sector lobbying of Ministers for privatisation as a means of further enhancing corporate profits.

Health insurers in Australia argue that the price of prostheses on the PL has added millions to annual health spending as insurers are paying more for prostheses than what is paid for the same devices obtained through the public hospital system. This in turn, increases the premiums for private health patients, and allegedly has resulted in many reducing their coverage level.

**IWG REPORT AND RECENTLY IMPLEMENTED REFORMS**

In early 2016, the Industry Working Group on Private Health Insurance Prostheses Reform (IWG) was formed by the government to investigate the PL in the “context of a broader review of private health insurance regulation”. Given Australia’s increasing ageing population, the IWG’s investigation focused not only on the PL framework but also the role of the PLAC. The findings of the report would hopefully bring about reform for the present and future benefit of Australia’s private health care system.

After the release of the IWG’s report in October 2016, the government announced a number of reforms that would be implemented which included: a reduction in the cost of cardiac devices on the PL by 10% and a reduction of 7.5% for hip and knee replacements. However this reform was implemented with the view of short-term progress rather than addressing the foundational flaws in the framework of the PL. While the reduction in prices has been implemented with the aim of lowering premiums, the reform did not consider the complexities of the system. The cuts did not address the crux of the issue and consequently there have been adverse impacts of manufacturers as it has resulted in market disruption.

**THE SENATE PROSTHESES LIST INQUIRY**

Private health insurers voiced their concerns over the flaws of PL’s framework. For example, Applied Medical have described the system as “very costly to the community without anyone being able to articulate the real benefit of it”. Private health care insurers further argued before the Senate Inquiry into the PL that the “inflated” prices of prostheses on the PL not only adversely impact the patients who reduce their coverage, but also the public system, which cannot accommodate the growing surplus of ageing patients requiring prostheses. Prostheses manufacturers argued their position to compete on price, and the Medical Technology Association of Australia argued that the PL is there to ensure that doctors pick the prosthesis that is appropriate for patients.

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18 Applied Medical, n 4, 8.
19 Community Affairs References Committee, Parliament of Australia, n 1, 27, [3.5]–[3.10]; Department of Health, n 7.
20 Community Affairs References Committee, Parliament of Australia, n 1, 27, [3.5]–[3.10]; Department of Health, n 7.
23 Applied Medical, n 4, 1.
24 Community Affairs References Committee, Parliament of Australia, n 1.
Three issues were commonly discussed in submissions to the Senate PL Inquiry. First, the inflated prices of prostheses compared to the public sector, domestic and international prices; second, the lack of transparency when fixing the price of products on the list; and third, the implications of the narrow definition of the term “prostheses”. These common criticisms of the system led many to describe the PL as a “segregated system” which renders insurers impotent. Submissions such as those from Healthscope noted a 4.8%–6.2% increase in annual premiums compared to the inflation rate of 1.3%–3.3% since 2010. Private health insurers argued that the increase in premiums is the result of insurers attempting to cover the inflated costs of prostheses devices on the list. As there is no tangible difference in the service provided by insurers, private health care patients are therefore downgrading their level of hospital cover or turning to the public system.

The Senate PL Inquiry listed as its terms of reference:

• the legislative structure of the PL;
• the role of the PLAC;
• the costs of prostheses for private patients versus public hospital patients;
• the potential for implementing a price reference model which considers international and domestic price differences;
• the appropriate pricing arrangements which may include mandatory price disclosure, value-based pricing and reference pricing;
• disclosure of costs associated with prostheses implantation, including the relevant services prior to and following the surgical implantation; and
• the relationships and interactions between the government and stakeholders regarding decision-making of prices.

The abovementioned terms were just a few of the issues the committee sought to address in its report. In examining the Senate’s report, the author will consider to what extent the committee addressed these terms of reference in its conclusions and recommendations.

The inflated prices of prostheses on the PL was perhaps one of the most prevalent concerns in submissions and has persisted over the last decade and several reviews. It was argued that international price benchmarking should be implemented to reduce the high costs private health insurers must pay for items on the PL, a cost which inevitably must be paid by private health insurance patients. Private Healthcare Australia compared the prices of prostheses in Australia to international prices and reported its findings in their submission. For example, Private Healthcare Australia found that in France, the same Consulta CRT-P model C3TRo1 triple-chamber pacemaker costs €4,000 (or AU$5,840) which in comparison costs $13,520 on the PL. This concern was addressed in the report, however, unsurprisingly it stated that manufacturers cautioned against comparing Australian prices with international prices given the differences in international health care to Australia’s system.
As previously mentioned, there have been mixed responses in the short months following the price reductions of 10% and 7.5% of prostheses devices.\textsuperscript{36} The most common concern however, as per the submission by Australian Orthopaedic Association, is that the arbitrary cuts to cardiac and hip prostheses showed a lack of understanding of the complexities of the prostheses market.\textsuperscript{37} Thus this was a concern that needed to be readdressed in the Senate’s report. Mr Andrew Stuart commented that:

The anecdotal data goes to, I think, a clear and broad and accepted understanding that the private sector prices are, on average, too high. But there is a risk in arbitrary price reductions that you hit the wrong target in the wrong way and you lose products from the Australian market.\textsuperscript{38}

Arguments were made by Healthscope, for a new pricing model to be implemented to reduce the burden of inflated prices on private health care patients.\textsuperscript{39} Many submissions including those from Healthscope and Applied Medical proposed a reference pricing system which takes into account international and public sector pricing.\textsuperscript{40} It was further submitted that reference pricing could be applied nationally as to reduce the inconsistencies currently being experienced in Australia.\textsuperscript{41} For example, Medibank noted that an implantable cardiac defibrillator costs $19,000 for Western Australia Health compared to the benefit for it on the PL being set at $52,000.\textsuperscript{42} This is a significant difference in price despite both being the same product and both being used and implanted in Australia.

Another well-noted concern found in submissions was the lack of transparency associated with the PL system.\textsuperscript{43} This concern applied to the transparency when it comes to the price fixing process of certain prostheses products as well as the transparency of PLAC decisions and relationships with stakeholders.\textsuperscript{44} The system was described by Mr Glenn Cross in the submission of AusBiotech as “opaque”.\textsuperscript{45} The report itself noted that this has been a concern raised over the last several inquiries into the PL, including submissions made in 2005.\textsuperscript{46} The view that the PLAC implements an unclear method to set prostheses benefits is also shared with the Australian Medical Association.\textsuperscript{47} However, it is important to consider, that the transparency cannot be achieved without making changes to arrangements in the current system.\textsuperscript{48}

Healthscope submitted that under the current system, the narrow definition of prostheses prevents a great number of new technologies from being added to the PL.\textsuperscript{49} For example, devices such as insulin implants, are not considered “prostheses” under the current stringent definition set by regulators.\textsuperscript{50}

\begin{thebibliography}{99}
\bibitem{37}Australian Orthopaedic Association, n 33, 3.
\bibitem{38}Evidence to Community Affairs References Committee, Parliament of Australia, Canberra, 16 March 2017, 69 (Andrew Stuart, Deputy Secretary, Department of Health, Committee Hansard); Community Affairs References Committee, Parliament of Australia, n 1.
\bibitem{39}Community Affairs References Committee, Parliament of Australia, n 1, 59–63, [5].
\bibitem{40}Healthscope, n 15, 4; Applied Medical, n 4, 10.
\bibitem{41}Healthscope, n 15.
\bibitem{42}Medibank Private Ltd, n 37, 2.
\bibitem{43}Medibank Private Ltd, n 37, 2.
\bibitem{44}Applied Medical, n 4, 22.
\bibitem{46}AusBiotech, n 45.
\bibitem{47}Australian Medical Association, Submission No 40 to Community Affairs References Committee, Parliament of Australia, \textit{Price Regulation Associated with the Prostheses List Framework}, 24 February 2017.
\bibitem{48}Evidence to Community Affairs References Committee, n 39, 70.
\bibitem{49}Healthscope, n 15, 4.
\bibitem{50}Healthscope, n 15.
\end{thebibliography}
coupled with the lack of efficacy reviews allegedly impacts clinical efficacy of the entire system as it is not geared towards technological development and rapid changes.\(^{51}\)

Another key issue raised in submissions was that of the duplication of products listed on the PL.\(^{52}\) In their submission, Bupa noted that 26% of items on the list had not been used since 2008.\(^{53}\) By reducing the list of prostheses on the PL, this could remove any ineffective devices that are unlikely to benefit health care patients.

**SENATE PL INQUIRY RECOMMENDATIONS**

While the report did reaffirm the longstanding position of health insurers that the prices for prostheses on the PL is too high, unfortunately, the committee stated that they did not have enough evidence to make a determination on which model of pricing would be best applicable for the PL.\(^{54}\) The committee did, however, recommend that the Department of Health investigate further into an appropriate benefit setting model for the PL in order to prevent public hospitals receiving undisclosed rebates from the insurer’s minimum benefit payment.\(^{55}\)

Consistent with the submissions of AusBiotech, the committee further recommended that an evidence-based approach was required, in order to reduce the costs of prostheses as soon as possible.\(^{56}\) Further to this, it was recommended that the PLAC review group pricing of a specific device when a new and cheaper product comes to the market.\(^{57}\) This approach, if implemented, could indeed provide influential in reducing the costs of prostheses, as it would expose any additional costs being charged to insurers which is not related to the cost of the prosthesis device alone.

The report recommended that the PLAC develop a formal work plan to publish which notes targets, timeframes and predations, and outcomes in order to improve stakeholders’ understanding of the process and encourage their active participation in reform and ongoing regulation.\(^{58}\) The committee recommended that the Health Minister publish a new Independent Hospital Pricing Authority data in order to demonstrate clearly the difference in price between prostheses in private and public hospitals and to determine whether this data could be used to amend prostheses prices.\(^{59}\) It was also suggested that the nature and costs associated with services of implanting prostheses be disclosed separately to the cost of the prosthesis itself.\(^{60}\) It is evident from submissions that the disclosure of public hospital pricing would enable insurers to see what aspect of the prostheses process their benefit sum is being contributed to, and where there is a discrepancy in price, the clear data would make a review of certain prices more achievable. Disclosing the price of services relevant would enable insurers to evaluate prostheses contracts in a transparent way.

Additionally, the committee recommended that where the Commonwealth introduces a prostheses registry, this should be legislated, published and collection of data for the registry be made compulsory.\(^{61}\) The author is of the opinion that if implemented, this recommendation would emphasise accountability and improve transparency of the benefit setting process of the PL. In turn, this could reduce secret and overinflated rebates being received by manufacturers and public hospitals.

\(^{51}\) Healthscope, n 15.

\(^{52}\) Community Affairs References Committee, Parliament of Australia, n 1, 59–63, [5].

\(^{53}\) Community Affairs References Committee, Parliament of Australia, n 1, 24, [2.79]–[2.84]; Bupa, n 17, 10.

\(^{54}\) Community Affairs References Committee, Parliament of Australia, n 1, 59–63, [5].

\(^{55}\) Community Affairs References Committee, Parliament of Australia, n 1.

\(^{56}\) Community Affairs References Committee, Parliament of Australia, n 1.

\(^{57}\) Community Affairs References Committee, Parliament of Australia, n 1.

\(^{58}\) Community Affairs References Committee, Parliament of Australia, n 1, 59–63, [5].

\(^{59}\) Community Affairs References Committee, Parliament of Australia, n 1, 59–63, [5].

\(^{60}\) Community Affairs References Committee, Parliament of Australia, n 1.

\(^{61}\) Community Affairs References Committee, Parliament of Australia, n 1.
The Senate Committee recommended that the PLAC seek to find an alternative price regulatory mechanism for prostheses that do not qualify to be on the PL, being devices which are implantable and do not require hospital admission and non-implantable devices to regulate costs for patients.62 Ostensibly, this would more adequately address stakeholder concerns that the definition of “prostheses” as per the PL is not broad enough and therefore inconsistent with its original purpose of providing accessible health care to Australians.

CONCLUSION

It was clear from submissions to the Senate and the final report, that the existence of the PL is widely supported and its importance is acknowledged despite flaws in its framework. Despite its 16 recommendations, it appears that the report ultimately fell short in addressing the extensive list of submitted reforms as well as the Senate’s own terms of reference. However, the 16 recommendations that were made should all be implemented in a large overhaul of the system, rather than attempted to fix one aspect of the framework at a time as evidenced in the clumsy October 2016 reforms. With greater transparency in the decision-making process of the PLAC, full disclosure of public and private prostheses costs and associated costs, the PL framework can be improved to create a more effective system of providing health care to patients. It is unfortunate that the committee did not make any reform recommendations in relation to incorporating international benchmarking as a model for the PL as this was perhaps one of the most frequently suggested reforms for the lower prices of prostheses. However, in order to maintain a system of affordable and accessible care to private and public patients, it is essential that amendments be made to the framework of the PL. It is not enough to arbitrarily reduce prices of certain prostheses, as was discovered by the price cuts in February 2017.63 Indeed, the system is complex, however, it stands to save millions from private health care expenditure, which will in turn prevent the inevitability of inflated costs falling back onto patients.

Private insurers are likely to be emboldened by this result to in future argue that if the minimum prices of the PL rise then inevitably this either will adversely impact patients in the form of increased premiums, or lead to the destruction of private health insurance.64 Such extravagant predictions of financial doom evoke Charles Dickens’s descriptions in Hard Times of the Coketown industrial barons’ proneness to claim, without proof or follow-through, that they would be “ruined” by every breeze of public interest regulation and would sooner “pitch their property into the Atlantic” than be held accountable for the personal or social consequences of their worship of the free market business model. The Atlantic no doubt these days contains much corporate detritus, particularly of the plastic and acidic kind, but few if any for-profit health care insurance businesses in Australia or elsewhere are likely to be compelled to have their property pitched there through regulatory attempts such as those manifesting in the PL to instil equity, fairness and respect for human dignity into private sector decision-making.

62 Community Affairs References Committee, Parliament of Australia, n 1, 59–63, [5].
63 Biotronik Australia Pty Ltd, n 22, 4.
64 Biotronik Australia Pty Ltd, n 22; Healthscope, n 15, 4.