

## Chapter 4

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 by unwittingly cutting too deep in a particular area or removing some of the current practices which involve clinical support. So, we are working in an area of a clear understanding that there is a problem but not a thorough dataset that provides a recipe.<sup>1</sup>

4.1 While all stakeholders agree that changes to the current Prostheses List (PL) framework are needed, it appears there is no one solution, and that no solution or suite of solutions will be agreeable to all stakeholders. As the Chair of the Prostheses List Advisory Committee (PLAC) has stated:

'If there is an answer to this issue that you are deliberating about, it is not going to be one answer; it is going to be multiple things in parallel including national and international reference prices... It is going to potentially be price disclosure if we can make that useful. It may be a number of other things.'<sup>2</sup>

4.2 This chapter will focus on trying to highlight some of the key areas identified by stakeholders where the current reforms could focus in attempting to address the historical and ongoing concerns in relation to prostheses prices for privately insured patients.

### **Do we need a Prostheses List?**

4.3 A number of stakeholders to this inquiry have suggested that the PL should be phased out over time to allow the market to determine what private health insurers pay for prostheses. Private Healthcare Australia (PHA) submitted that the current Prostheses List framework is 'winning the battle but losing the war: price inflation is under control, but reimbursement levels remain significantly higher than other comparable health systems.'<sup>3</sup>

4.4 In their Pre-Budget Submission 2017–18, PHA recommended that, in addition to rapid implementation of the proposed PL reform agenda in 2017–18, the

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1 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 69.

2 Professor Terry Campbell, Chair, Prostheses List Advisory Committee, *Committee Hansard*, 16 March 2017, p. 56.

3 Private Healthcare Australia, *Submission 7*, [p.7].

government 'should have an explicit deadline to exit regulation of medical device benefits in the private health sector.'<sup>4</sup>

4.5 The majority of submitters and witnesses, however, have argued that some form of PL is necessary and desirable, particularly given the complex system in which prostheses are selected, purchased, paid for and reimbursed when a patient is privately insured.

4.6 The Department of Health (department) provided the following figure to show the impact of deregulation and re-regulation, showing that re-regulation coincided with stabilisation of the average benefit paid per prosthesis.

Figure 4.1: Prostheses expenditure and average benefit per prosthesis – 1989/90 to 2015/16

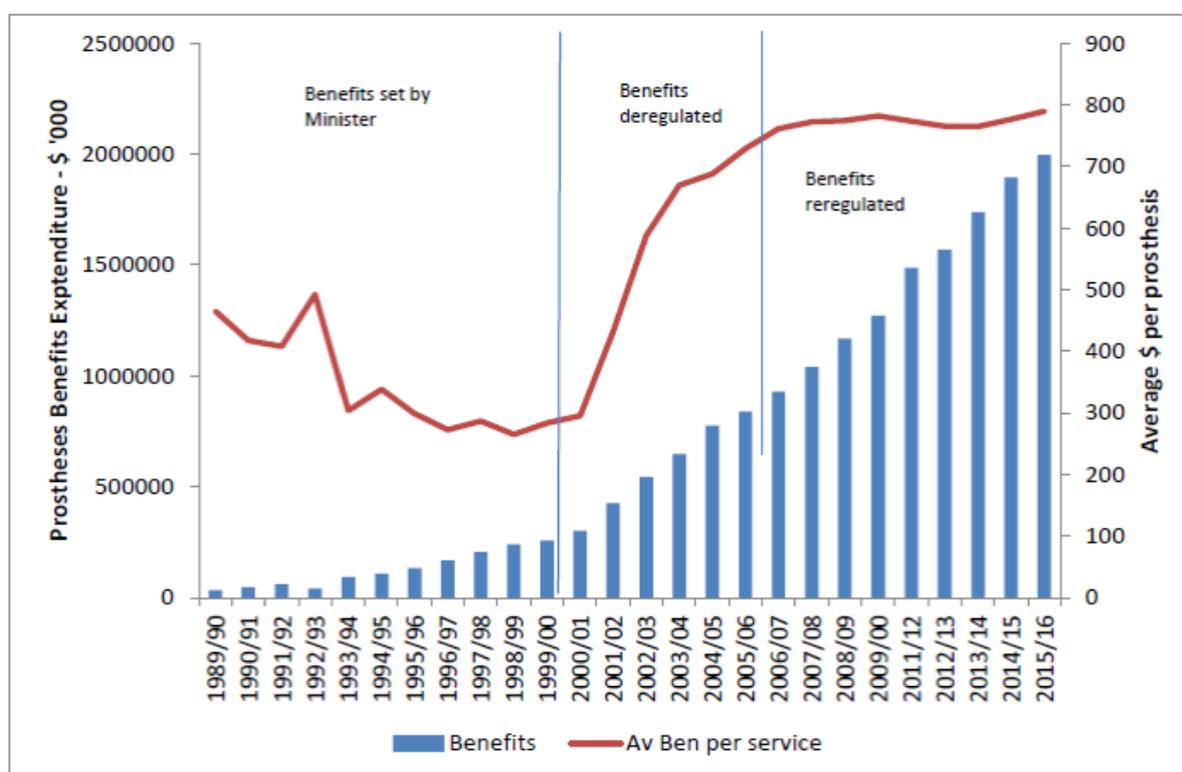


Figure 2: Prostheses expenditure and average benefit per prosthesis – 1989/90 to 2015/16

Sources:

Private Health Insurance Administration Council – *Operations of Registered Health Benefits Organisations Annual Reports* (1989/90 to 2005/2006)

Private Health Insurance Administration Council – *Operations of Private Health Insurers Annual Reports* (2006/07 to 2013/14)

Australian Prudential Regulation Authority - *Operations of Private Health Insurers Annual Reports* (2014/15 and 2015/16)

Source: Department of Health, *Submission 38*, p. 11.

4 Private Healthcare Australia, Pre-Budget Submission 2017-18, 19 January 2017, <https://www.treasury.gov.au/~media/Treasury/Consultations%20and%20Reviews/Consultations/2016/2017%20PreBudget%20submissions/Submissions/PDF/Private%20Healthcare%20Australia.ashx> (accessed 19 April 2017), p. 17.

4.7 Ramsay Health Care Limited stated that:

The Prostheses List was introduced to address issues arising from the previously deregulated environment, which saw rapid increases in prostheses pricing. The Prostheses List has also resulted in additional assurances of device safety and efficacy.<sup>5</sup>

4.8 Catholic Health Australia (CHA) members support the exploration of proposals to provide a more competitive approach to benefit setting whilst maintaining the benefit of certainty and access to technology provided by the PL and PLAC processes:

The PL and PLAC have been instrumental in slowing the rising costs of devices and ensuring that patients continue to have access to appropriate and up to date technologies. CHA recommends that the PL and existing architecture of the PLAC be maintained and incorporated into any future model that is adopted by the Government and private health industry.<sup>6</sup>

4.9 All stakeholders have indicated a need for change. The degree of change, from moves to improve administration and transparency of PLAC, the PL and health technology assessment (HTA) processes more broadly, through to abolition of government regulation, is where there is little consensus between stakeholders.

### **Review of PL listing criteria**

4.10 One of the key areas for reform of the PL framework being undertaken by the PLAC is a review of the criteria for listing on the PL. PLAC has listed the desired outcomes of the criteria review as:

- Privately insured Australians have access to medical devices that meet their healthcare needs through their private health insurance.
- Evidence requirements for listing on the Prostheses List are appropriate and defensible.<sup>7</sup>

4.11 The proposed activities to review the definition of prostheses include comparing the current definition with those used in comparable processes and regulatory arrangements, and to consult on any proposed changes to this definition, including in relation to any impacts and transition arrangements.<sup>8</sup>

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5 Mr Christopher Rex, Managing Director, Ramsay Health Care Limited, answers to questions on notice, 31 March 2017 (received 13 April 2017).

6 Catholic Health Australia, *Submission 25*, p. 2.

7 Department of Health, *Submission 38*, Attachment F, [p. 2].

8 Department of Health, *Submission 38*, Attachment F, [p. 2].

### *Defining prostheses*

4.12 A broad range of stakeholders to this inquiry have called for a change to the definition of prostheses used for regulation of prostheses prices in the private sector.<sup>9</sup> In its report, the Industry Working Group on Private Health Insurance Prostheses Reform (IWG) stated that they had agreed that the current definition of prostheses should be reviewed, particularly given 'the rapid development of novel medical technology.'<sup>10</sup>

4.13 Changes to the definition of prostheses have been argued for a number of reasons. The varying reasons help to highlight some of the issues that stakeholders consider need to be addressed through the current reform process. The key reasons and the arguments supporting them have been included below.

4.14 The main argument put by submitters to this inquiry is that the definition of prostheses should include medical devices that do not fit the current definition of prostheses but which provide superior outcomes. Cochlear Limited submitted:

A revision of the definition of 'prostheses' and the introduction of a benefit re-evaluation process as part of the Prostheses List framework is recommended as way of ensuring the most cost effective interventions are provided and appropriate reimbursement benefits are maintained.<sup>11</sup>

4.15 Dr Janet Wale, formerly a consumer representative on the PLAC, states that there is inequitable access to medical devices for privately insured patients in private hospitals, in part due to how prostheses are defined for inclusion on the PL. She argues that, 'It is time that we work to develop consensus on an easily understood, publicly defensible definition.'<sup>12</sup>

4.16 In her submission, Dr Wale provides a list of medical devices, for example, cardiac ablation catheters, which, despite having an evidence base for their use, are unavailable in private hospital settings as they cannot be included on the PL.<sup>13</sup> This view is supported by many other stakeholders.<sup>14</sup>

4.17 Device manufacturer, Applied Medical, argues that the current definition of prostheses goes beyond the original intention of the PL, and now includes 'low value

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9 See for example: Medical Technology Association of Australia, *Submission 2*, p. 21; Cochlear Limited, *Submission 8*, p. 14; Catholic Healthcare Australia, *Submission 25*, p. 3; Stryker Australia Pty Ltd, *Submission 29*, p. 9; Australian Medical Association, *Submission 40*, p. 4; Healthscope, *Submission 42*, p. 6.

10 Department of Health, *Submission 38*, Attachment E, p. 4.

11 Cochlear Limited, *Submission 8*, p. 4.

12 Dr Janet Wale, *Submission 11*, [p. 2].

13 Dr Janet Wale, *Submission 11*, [p. 3].

14 See for example: MTAA, *Submission 2*; Cochlear Limited, *Submission 8*; Catholic Health Australia, *Submission 25*.

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surgical consumables which clearly do not meet the criteria considered by Parliament when the regulation of prostheses was first adopted.<sup>15</sup>

4.18 Applied Medical argue that the definition of prostheses be reviewed, but with a view to rationalising the PL. Applied Medical argues that expanding the PL to include other items ultimately will not work, because:

there will always be boundaries to what is, and is not, included on the Prostheses List, regardless of which definition of what constitutes a 'prosthesis' is selected. The inherent nature of the regulatory framework is such that there will always be distortions in patient and physician choice as a result of a misalignment of financial costs.<sup>16</sup>

4.19 Similarly, medical device sponsor, Biotronik, argues that items on the PL, for example, coronary stents, may be used in preference to items that are not eligible for listing, for example, drug-eluting balloon therapies, due to the 'impact on provider revenues.'<sup>17</sup>

4.20 The committee has also heard that amending the definition of prostheses may help in addressing one of the most pressing issues raised by stakeholders during the course of this inquiry. LifeHealthCare states that:

incentives are being used by private hospitals to fund prostheses that are not currently included on the PL (e.g. cardiac ablation catheters or fractional flow reserve) due to limitations in PL definitions. We believe this should be addressed by expanding the definition of a prosthesis to include non implantable devices rather than relying on incentives, that are not transparent, in order to gain access to these prostheses.<sup>18</sup>

4.21 This view is shared by another sponsor, Cochlear Limited. Cochlear has suggested that, in addition to redefining prostheses, the role of the Health Economic Sub Committee (HESC) of the PLAC should be expanded so that it can, among other things, provide 'evaluation of cost effective interventions that utilise medical devices that fall outside the current definition of "prostheses"'.<sup>19</sup>

4.22 One submission has suggested expanding the definition of prostheses through the creation of a 'Part D' for the PL, to enable inclusion of medical devices which cost over \$300 and which are single use but are not implanted.<sup>20</sup>

4.23 The IWG noted in its report that representatives from the private health insurance sector argued that consideration of a review of the definition of prostheses 'must only occur in the context of a revision of the benefit setting.'<sup>21</sup>

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15 Applied Medical, *Submission 41*, Attachment B, p. 11.

16 Applied Medical, *Supplementary submission 41*, p. 4.

17 Biotronik Australia, *Submission 22*, p. 6.

18 Joint submission from four Australian medical device manufacturers and distributors, *Submission 39*, Attachment 1, [p. 2].

19 Cochlear Limited, *Submission 8*, p. 10.

20 Name withheld, *Submission 43*, [p. 4].

***What should legitimately be included in setting a benefit level?***

4.24 Considerable debate has occurred during this inquiry in relation to whether the benefit level for the reimbursement of prostheses should include support services associated with a prosthesis.

4.25 Mr Chris Rex, Chief Executive Officer, Ramsay Health Care Limited, questioned the current system thus: 'it has always intrigued me—and continues to do so—why prostheses are actually treated separately from all other cost inputs into procedures.'<sup>22</sup>

4.26 The department has advised that, currently, applications to list a new device on the PL are required to propose a benefit for the device which would cover the costs of both producing and supplying the device to the patient. In some cases, ancillary services and after care are also included in the benefit.<sup>23</sup>

4.27 Biotronik Australia Pty Ltd, which manufactures and supplies cardiac and combined drug and device therapies, notes that in relation to the current system:

the PL benefits were negotiated on the basis that the benefit should include all costs associated with delivery, implantation and support of the prostheses and hence the publicised significant benefit differences between public and private are justified.<sup>24</sup>

4.28 Biotronik argues that there are sound reasons why services are included in the costing of prostheses for the PL, citing as an example where these services are included in professional bodies' standards of care for patients, such as those set by the Cardiac Society of Australia and New Zealand. Biotronik states that in public hospital settings these services are usually provided through clinics in the hospital, but in the private sector, are often delivered by surgeons with the assistance of the medical device sponsors.<sup>25</sup>

4.29 Other medical device sponsors, for example, Applied Medical, state that it provide the same type and level of service in relation to their PL devices regardless of which setting is used, public or private hospital.<sup>26</sup>

4.30 Cochlear Limited also submitted that it provides the same level of professional training, and patient management, and support in both public and private hospital settings, and listed the annual cost of doing so in its submission.<sup>27</sup>

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21 Department of Health, *Submission 38*, Attachment E, p. 9.

22 Mr Chris Rex, Chief Executive Officer, Ramsay Health Care, *Committee Hansard*, 31 March 2017, p. 12.

23 Department of Health, answers to written questions on notice, 16 April 2017 (received 26 April 2017).

24 Biotronik Australia Pty Ltd, *Submission 22.1*, p. 6.

25 Biotronik Australia Pty Ltd, *Submission 22.1*, p. 6.

26 Applied Medical, *Supplementary submission 41*, p. 7.

27 Cochlear Limited, *Submission 8*, p. 12.

4.31 However, Cochlear, which does not have high a volume of sales, supplies prostheses to public and private hospitals under the same purchasing arrangements, that is, on individual orders per patient.

4.32 Cochlear argues that product management and support of devices on the PL should be factored in to the benefit levels set.<sup>28</sup>

4.33 AusBiotech, a network of Australian small and medium companies in the life sciences industry, including medical technology, argues that any evaluation of and changes to benefit setting methodologies should consider that the:

Totality of the service delivered is taken into account when determining the value of the prosthesis benefit for a product, i.e., not only 'clinically relevant requirements', as mentioned by the IWG, but also other aspects of service (e.g., education provided), the relative size of the private market, attractiveness of Australia for launching new technologies, etc.<sup>29</sup>

4.34 The committee notes that this appears particularly relevant for the small to medium Australian medical device sponsors, which may supply prostheses to both sectors without significant variation in price, and which may be most impacted by significant changes to the current benefit setting framework.

4.35 In its evidence, the private hospital operator, Healthscope Ltd, stated that it negotiates contracts with medical device sponsors which enable the cost of handling of prostheses to be covered through those contracts.<sup>30</sup>

4.36 Healthscope Ltd also indicated that prior to the current PL framework:

there used to be a handling fee of five per cent applied to the value of a prosthetic device that was designed to compensate the hospital for the cost we incur in moving devices in and out of the hospital and the like. From a Healthscope perspective, if the outcome from this review was more transparency on pricing and some form of handling fee in that range that was designed to compensate hospitals for costs incurred, that would be an outcome that we think we would not be uncomfortable with.<sup>31</sup>

### ***Committee view***

4.37 The committee notes that the majority of stakeholders have supported a review of the definition of prostheses and reconsideration of what should be included in setting a benefit level for prostheses reimbursement. The committee also notes that the PLAC has included a review of the listing criteria, including revising the definition of prostheses and longer term work on revising how benefit levels are set, in its work plan.

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28 Cochlear Limited, *Submission 8*, pp. 11-13.

29 AusBiotech Ltd, *Submission 15*, p. 4.

30 Mr Michael Sammells, Chief Financial Officer, Healthscope Ltd, *Committee Hansard*, 31 March 2017, p. 7.

31 Mr Michael Sammells, Chief Financial Officer, Healthscope Ltd, *Committee Hansard*, 31 March 2017, p. 8.

4.38 In undertaking a review of the definition of prostheses and other fundamental changes to the current system, consideration should be given to the range of issues raised by stakeholders, through this inquiry and other earlier reviews.

4.39 The committee notes that several submitters commented on the use of medical devices that are not surgically implanted, or that do not require hospitalisation to implant.<sup>32</sup> There is a need for consideration of how these kinds of devices can be reimbursed.

4.40 The committee considers that opportunities to redefine the criteria should not be limited to expanding the definition to broaden the kind of devices included.

4.41 In particular, it is important for the PLAC and the department be mindful of, and take steps to address, the broader implications of changing the definition of prostheses, within the context of other proposed reforms. Consideration should also be given to how changes to the definition and listing criteria may address some of the ongoing issues raised by submitters, including finding a more transparent and robust way of setting benefit levels.

### **Setting a PL benefit level – which model?**

4.42 In addition to reviewing the definition of prostheses and the criteria for listing, government reforms also include consideration of alternative models for the setting of benefits for items on the PL.

4.43 The IWG was presented with some potential options, including international reference pricing, price benchmarking using weighted averaging of public and private sector prices, and the price disclosure model used for the Pharmaceutical Benefits Scheme (PBS). Upon consideration of the various models presented to it, the IWG agreed, in relation to possible models for benefit setting, that:

Should Government seek medium term benefit reductions across the PL, it would be appropriate to consider legislating a price disclosure system for prostheses, encompassing both public sector and private sector medical device pricing; [and] ...reference pricing taking into account domestic and relevant international prices, be considered as a mechanism to set the PL benefit.<sup>33</sup>

4.44 Work is now under way to research and identify possible models for consideration by the PLAC, as outlined in Chapter 3 of this report. A consultant has been engaged to research and compare:

- pricing models, including reference pricing and market based approaches;
- international and domestic benchmarking;
- price disclosure; and

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32 See for example: Australian Diabetes Society and Endocrine Society of Australia, *Submission 9*; Dr Janet Wale, *Submission 11*; AusBiotech, *Submission 15*; Medtronic, *Submission 36*.

33 Department of Health, *Submission 38*, Attachment E, p. 7.

- benefit setting frameworks.<sup>34</sup>

4.45 A report by the consultant, providing a comparative analysis of benefit setting models, was released by the department on 4 May 2017. The report looks at international and domestic examples of benefit setting models and price disclosure that will assist the PLAC in its work.<sup>35</sup>

4.46 The committee notes that there is also concurrent work being undertaken by the PLAC itself, through consideration of applications to list novel devices on the PL:

There are one or two [PL applications for novel devices] that are in train where we are using it very much as the new frontier, if you like. They are new and they do not clearly fit into any of the existing groupings, and that is where I am working with my colleagues in MSAC [Medical Services Advisory Committee] and the TGA [Therapeutic Goods Administration], because I think what we need to do there is to do a proper evaluation, and in some cases that has already been done by MSAC as part of their work for deciding on MBS item numbers et cetera, coming up with a cost-effective price.<sup>36</sup>

4.47 The department has stated that for new prostheses to be used within newly devised medical processes, the PLAC will take advice from the MSAC on the cost effective price of the device in the context of the whole healthcare service.<sup>37</sup>

4.48 The committee notes that the desired outcome of current work being undertaken by the PLAC is that '[b]enefits on the Prostheses List reflect the appropriate reimbursement costs of supplying medical devices to patients.'<sup>38</sup> In relation to adopting new benefit setting models, there appear to be a wide variety of options even within a particular type of pricing model, and possible combinations of models that can be used.

### ***Reference pricing***

4.49 The IWG and the PLAC have indicated that consideration of reference pricing, with possible domestic and international benchmarking, is being undertaken to identify a possible longer term benefit setting model.

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34 Department of Health, *Submission 38*, pp. 12-13.

35 Health Economics Unit, Centre for Health Policy, Melbourne School of Population and Global Health, University of Melbourne, *Prostheses Benefit Setting Framework: Comparative analysis of benefit setting models*, Department of Health, March 2017, [http://www.health.gov.au/internet/main/publishing.nsf/Content/EE9D7DA6EA42BDE0CA257BF00020623C/\\$File/PROSTHESES%20BENEFIT%20SETTING%20FRAMEWORK\\_SENT\\_DOH\\_1%20V2.PDF](http://www.health.gov.au/internet/main/publishing.nsf/Content/EE9D7DA6EA42BDE0CA257BF00020623C/$File/PROSTHESES%20BENEFIT%20SETTING%20FRAMEWORK_SENT_DOH_1%20V2.PDF) (accessed 4 May 2017).

36 Professor Terry Campbell, Chair, Prostheses List Advisory Committee, *Committee Hansard*, 16 March 2017, p. 57.

37 Department of Health, answers to written questions on notice, 16 April 2017 (received 26 April 2017).

38 Department of Health, *Submission 38*, Attachment F, [p.1].

4.50 In effect, reference pricing would include comparing the price of prostheses in the private sector in Australia with other markets, potentially domestically (in the public health sector), or internationally and setting a benefit level that was in line with comparable benchmarks.

4.51 There has been a mixed response to this suggested model. Some stakeholders, notably medical device sponsors, have been critical of this model, outlining the challenges of finding suitable comparators, either domestically or internationally.<sup>39</sup>

4.52 Some medical device sponsors have indicated that it could usefully be used as an input to a decision on benefit levels, but should not be the only consideration, and would necessitate alternative approaches for new devices where there is no comparator. In its submission, Cochlear Limited stated that:

International reference pricing (IRP) may be used as an input into the benefit setting process for new technologies that have not yet been launched in Australia. However, due to the complexity of adjusting for differences in health care systems across multiple jurisdictions, there may be significant challenges in defining algorithms to adjust median IRPs to inform benefit levels of prostheses in the Australian Private Health Insurance environment.<sup>40</sup>

4.53 Healthscope Limited supports the introduction of reference pricing 'while having regard to the different market dynamics in other countries.'<sup>41</sup>

4.54 Private health insurers consider reference pricing to be a suitable option that has been successful in other countries and could be applied in Australia:

Reference pricing is a well-accepted system which is currently used in several countries. For instance, Japan has employed international reference pricing for over a decade. France, Italy, the Czech Republic, Russia and the U.K. are other exemplars of domestic or international reference pricing. In applying this model to prostheses pricing in the Australian health system, the proposed reform would closely resemble similar recent reforms to the Pharmaceutical Benefits Scheme (PBS) where more stringent requirements on price disclosure and international references are expected to yield \$3.1 billion in savings by 2018.<sup>42</sup>

4.55 Some medical device sponsors have recommended that any new benefit setting model that relies on comparisons between different markets, in particular the domestic public and private hospital sectors, should use information at a billing code level.<sup>43</sup> This would in effect mean that each individual medical device would be compared to itself.

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39 MTAA, *Submission 2*, p. 13.

40 Cochlear Limited, *Submission 8*, p.15.

41 Healthscope, *Submission 42*, p. 6.

42 Private Healthcare Australia, *Submission 7*, [p. 12].

43 See, for example: Styker Australia, *Submission 29*; Joint submission from four Australian medical device manufacturers and distributors, *Submission 39*.

4.56 However, the committee notes that this issue was dealt with as part of the 2009 Review of Health Technology Assessment in Australia, which found that this approach adds unnecessary administrative burden and recommended that groupings of devices be used as the basis for any benefit setting.<sup>44</sup>

4.57 As referred to in the PHA submission above, the current reform process being undertaken by PLAC includes consideration of the model developed for the PBS, which is also administered by the department.

***Price Disclosure – the Pharmaceutical Benefits Scheme pricing model***

4.58 It has been suggested that the reforms that have been undertaken to address issues with the pricing and reimbursement of pharmaceuticals in Australia might also be applied in reforming the PL framework. The representative body for not-for-profit private health insurers, hirmaa, sees merit in applying a similar model of price disclosure to the PL:

We look to the PBS system as having some good examples of what we could do in this space. We do not see a big difference between pharmaceuticals and devices. We think there should be mandatory legislated price disclosure consistent with the PBS or maybe even stronger, with very harsh penalties for not disclosing.<sup>45</sup>

4.59 Some caution has been expressed by other stakeholders, including CHA, in adopting a model based on the reimbursement of medicines, given the inherent differences between medicines and medical devices:

I think there are challenges with that. Drugs—legal drugs—take a long time to come to market. They have a patented molecule, and generally that molecule will remain unchanged for years and years. If you look at prosthetics—let us take a surgical stapling device—it is a little bit like a car: each year there will be slight modifications to it, whether they are true enhancements or not, the model number will change, the name will change and there will always be this challenge of, 'Is it the same circular stapler that was listed two years ago?'<sup>46</sup>

4.60 AusBiotech has similarly urged caution, and highlights the cost of administrative costs to sponsors, particularly small to medium companies:

This [PBS] model has the potential to improve price transparency and reduce rebates for existing categories of products. However, the implementation and administration of this system would be expensive and our members have expressed concern that the burden of these costs would be passed on to industry.<sup>47</sup>

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44 Department of Health, *Submission 38*, p. 10.

45 Mr Matthew Koce, Chief Executive Officer, hirmaa, *Committee Hansard*, 16 March 2017, pp. 19-20.

46 Dr Simon Woods, Executive Director, Malvern, Cabrini, *Committee Hansard*, 16 March 2017, p. 31.

47 Ausbiotech, *Submission 15*, p. 8.

4.61 Applied Medical states that although price disclosure might be suitable as part of a range of reforms, on its own it would not 'deliver the price reductions necessary to see Australians paying market based competitive rates for prostheses in the private health system.'<sup>48</sup>

### ***Committee view***

4.62 The committee understands that there are potentially several models that may be used in the Australian context to help maximise cost effectiveness and access to prostheses for privately insured patients.

4.63 It is clear from the evidence presented to this inquiry that stakeholders are very aware of the options currently under consideration but there are different views on the effectiveness of the various options.

4.64 The committee acknowledges that stakeholders have made significant efforts to critique the various options and considers it important for any further research and analysis to include consideration of this work in arriving at final options for the government to consider.

4.65 It should be noted, however, that while no one model will suit all stakeholders, there may need to be compromise and negotiation to ensure that the final model is workable and delivers desired outcomes.

### ***Whole of episode payment reimbursement***

4.66 Some submissions have signalled a desire to move eventually to a whole of episode reimbursement model.<sup>49</sup> For example, PHA stated that a:

longer-term opportunity is to integrate prostheses costs into an episode-based payment. Agreeing on a predetermined reimbursement per procedure (e.g. per MBS item) would create stronger incentives for manufacturers to compete on price and improve the sustainability of the overall health system.<sup>50</sup>

4.67 The MTAA does not support a move towards using payments which would set a reimbursement level for the whole 'episode of care'. The MTAA states that using such a model:

encourages the pursuit of the lowest cost product as opposed to the highest value product (in terms of the contribution to the patient's health outcome). This will reduce the number of innovative products available in the private sector and eventually erode the value of private insurance to consumers, which, based on a Government survey from 2015 was already a significant concern.<sup>51</sup>

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48 Applied Medical, *Supplementary submission 41*, p. 17.

49 See for example: Private Healthcare Australia, *Submission 7*; Applied Medical, *Supplementary submission 41*.

50 Private Healthcare Australia, *Submission 7*, [p. 8].

51 Medical Technology Association of Australia, *Submission 2.1*, p. 5.

4.68 Catholic Health Care indicated that benefit levels based on episodes of care are likely to be the future, but there is a long way to go:

Inevitably, I think, the health industry should move to episodic, value based purchasing. The challenges are that, in the private sector, the vast majority of doctors are not employed by and are remunerated separately from the hospital. Often their incentives are quite different to those for the hospitals. That is why it really would require a restructure of both the Medicare system and the health insurance system.<sup>52</sup>

### *Committee view*

4.69 The committee acknowledges the extensive work undertaken by stakeholders in considering the best approach in reforming the PL and in arriving at a better way of considering the appropriate reimbursement level for prostheses paid for through private health insurance.

4.70 It is clear that there are a number of options that might be suitable, and choosing the right model should be a process undertaken with consideration of the research, analysis and comparison that has been undertaken by stakeholders, in addition to that being undertaken by Professor Clarke on behalf of the PLAC.

4.71 Whichever method is chosen for the determination of benefit levels to be paid by private health insurers, or whether the government ultimately chooses to let the market decide what prices are paid by private health insurers for medical devices, it is hoped that the Department of Health and the various committees genuinely work together in a more coordinated way, and with effective consultation to ensure the best possible outcome of the current reform process, and ultimately, a better deal for taxpayers and consumers.

4.72 It is clear from the submissions and other evidence received by the committee that there are many inter-related issues for consideration through the reform process currently under way. There are significant problems with the current model for the reimbursement of prostheses through the PL, many of which have been raised on more than one occasion through reviews and also through the research and analysis undertaken by stakeholders themselves.

4.73 As Stryker Australia has noted in its submission:

It is not possible to reform any individual component of the health system without consideration of flow on impacts to other stakeholders. As such, any reform must involve extensive consultation and a strong evidence-based approach. Ad hoc or reactive reform enacted under short term political or media pressure is unlikely to achieve the overriding goal of sustaining a high quality and affordable healthcare system.<sup>53</sup>

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52 Dr Simon Woods, Executive Director, Malvern, Cabrini, *Committee Hansard*, 16 March 2017, p. 32.

53 Stryker Australia, Pty Ltd, *Submission 29*, p. 9.

## Data collection

### *Device registries*

4.74 The committee heard that the development of device registries, such as the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), have played an important role in improving outcomes of surgeries and identifying devices which were not performing to the same standards as comparable devices. For example, the AOA submitted that the AOANJRR had shown that large-head metal-on-metal hip joint 'lookalike prostheses' were not performing to the same standards as the original product.<sup>54</sup>

4.75 In its final report the IWG agreed that there should be a formalised process of post-marketing review and considered the absence of this process to be a major failure of the current PLAC arrangements. In particular, the IWG noted that the PLAC has failed to delist devices where there was evidence from current registries of devices not performing as well as comparable products.<sup>55</sup>

4.76 However, the IWG also noted that the PLAC is not currently resourced to introduce a post-marketing review process. The IWG supported more coordination between the PLAC, registries and the TGA to identify both superior and inferior devices.<sup>56</sup>

4.77 Currently registries such as the AOANJRR are maintained and funded by the applicable medical college.<sup>57</sup> The department levies device manufacturers and passes this funding on to the relevant college.<sup>58</sup> The information provided to inform the registry is voluntary but the colleges receive a high percentage of involvement as this is best practice amongst contributors to the registry.<sup>59</sup>

4.78 The department noted that in the future such information could be automatically captured by the e-health system, stating that:

These things will need to be built in the e-health system, but there is a future pathway to every operation and every device being in a system... and

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54 Dr Peter Lewis, Deputy Director, Australian Orthopaedic Association National Joint Replacement Registry, Australian Orthopaedic Association, *Committee Hansard*, 16 March 2017, p. 46.

55 Department of Health, *Submission 38*, Attachment E, p. 10.

56 Department of Health, *Submission 38*, Attachment E, p. 10.

57 Ms Tracy Duffy, Assistant Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 66.

58 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 66.

59 Ms Tracy Duffy, Assistant Secretary, Department of Health, *Committee Hansard*, 16 March 2017, p. 66.

then being able to capture down the track whether there is re-hospitalisation in respect of those issues and devices.<sup>60</sup>

### ***Independent Hospital Pricing Authority***

4.79 The IHPA collects data from both public and private hospitals in two separate collections through the National Hospital Cost Data Collection (NHCDC) process. The NHCDC includes information on costs associated with prostheses and other medical devices.<sup>61</sup>

4.80 The data provided by states and territories on public hospitals is used to determine the National Efficient Price which provides a price signal or benchmark for the efficient cost of providing public hospital services. The public sector NHCDC captures 90 per cent of acute admitted hospital activity.<sup>62</sup>

4.81 Information from private hospitals is provided to IHPA on a voluntary and confidential basis and accounts for approximately 60 per cent of total overnight private hospital separations.<sup>63</sup>

4.82 To ensure consistency of data provided by public hospitals, the IHPA conducts quality assurance and validation processes, including an independent financial review.<sup>64</sup> However, data provided by private hospitals is not subjected to such processes.<sup>65</sup>

4.83 As outlined in Chapter 2, there is a significant difference between the prices paid for prostheses in public and private hospitals and there is a lack of transparency around the rebates and discounts received by private hospitals.

4.84 In answers to questions on notice, the IHPA provided information on the costs of prostheses provided in private hospitals and noted a number of caveats around comparison of data between public and private hospitals.<sup>66</sup> In particular, the committee notes that there is a year's gap between the information available on public and private hospitals, that private hospital data is not subject to independent financial review and that the private hospital data is based on an older version of the Australian Refined Diagnosis Related Groups.<sup>67</sup>

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60 Mr Andrew Stuart, Deputy Secretary, Department of Health, *Committee Hansard*, 16 March 2017, pp. 66-67.

61 IHPA, *Submission 37*, [pp. 1-2].

62 IHPA, *Submission 37*, [p. 1].

63 IHPA, *Submission 37*, [p. 1].

64 IHPA, *Submission 37*, [p. 1].

65 IHPA, answers to questions on notice, 15 March 2017 (received 3 April 2017).

66 IHPA, answers to questions on notice, 15 March 2017 (received 3 April 2017).

67 Australian Refined Diagnosis Related Groups (AR-DRGs) is an Australian admitted patient classification system which provides a clinically meaningful way of relating the number and type of patients treated in a hospital to the resources required by the hospital. Each AR-DRG represents a class of patients with similar clinical conditions requiring similar hospital services. See: <http://www.aihw.gov.au/hospitals-data/ar-drg-data-cubes/> (accessed 11 May 2017).

**Committee view**

4.85 The committee believes that, in the absence of a formalised post-marketing review by the PLAC, device registries play a useful role in identifying prostheses which are not performing to an acceptable standard.

4.86 The committee supports better coordination between the PLAC, device registries and the TGA to identify both superior and inferior devices and to consider delisting poor performing devices from the PL.

4.87 The committee notes that the e-health system may have the capacity to play the role of a single device registry in the future and that this would enable the automatic collection of information on devices.

4.88 The committee notes that there are a number of factors which contribute to a lack of transparency around prostheses pricing. Notably, information from private hospitals is provided on a voluntary and confidential basis and there are a number of caveats attached to private hospital's data which limit the ability to compare public and private hospital data.

**NDIS transition arrangements**

4.89 The terms of reference for this inquiry include consideration of any implications for prostheses recipients of the National Disability Insurance Scheme (NDIS) transition period. The NDIS enables people with a disability to access support through individualised plans.

4.90 The Department of Health submitted that 'it is unlikely that the transition period of the NDIS will have any significant implications for recipients of prostheses funded by the prostheses listing arrangements.'<sup>68</sup>

4.91 However, one submission to this inquiry did raise some concerns in relation to the transition of Australian Hearing clients to the NDIS. Cochlear Limited indicated that there is:

lack of clarity regarding the transition of Australian Hearing (AH) clients to the National Disability Insurance Scheme (NDIS). This is resulting in confusion and uncertainty individuals, providers and suppliers.<sup>69</sup>

4.92 The Cochlear submission states that '[n]o solution has been defined for the ongoing support of some of Australia's most severely hearing impaired and financially vulnerable - those AH clients > 65 years.'<sup>70</sup>

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68 Department of Health, *Submission 38*, p. 13.

69 Cochlear Limited, *Submission 8*, p. 4.

70 Cochlear Limited, *Submission 8*, p. 4.