Chapter 1
Introduction

> The Prostheses List was introduced as measure to stabilise uncontrolled and uncontained growth in the private sector, however it resulted in a system that is complicated and not well understood.[1]

1.1 The Australian healthcare system operates under a mixed model of private and public health and hospital services. Australians with private health insurance who are recipients of prostheses may choose to receive treatment as private patients in either private or public hospitals.

1.2 Where prostheses are provided to private patients in either a private or public hospital, the price paid for the prostheses by private health insurers is set by the Prostheses List (PL). The PL is regulated by the Australian government and requires that private patients have no out-of-pocket expenses for prostheses.

1.3 Private health insurance premiums have increased by approximately 5.6 per cent each year in the last ten years leading to concerns about private health insurance becoming increasingly unaffordable.[2] For the first time since the government introduced measures to encourage the uptake of private health insurance, participation rates are decreasing.[3]

1.4 The price of prostheses on the PL has been identified by the Government and private health insurers as a factor in the rising price of health insurance premiums.[4] In October 2016 the Government announced a number of changes to the PL in an effort to ease pressure on private health insurance premiums.[5] The response to these changes has been mixed with private health insurers claiming they do not go far enough and manufacturers raising concerns about the lack of evidence for the changes and the impact on the prostheses industry.[6]

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1 Australian Medical Association, *Submission 40*, p. 2.

2 Medibank Private, *Submission 14*, p. 3.

3 Mr Matthew Koce, Chief Executive Officer, hirmaa, *Committee Hansard*, 16 March 2017, p. 18.

4 See, for example: Private Healthcare Australia, *Submission* 7; Medibank, *Submission 14*; BIB, *Submission 16*; HBF, *Submission 27*; HCF, *Submission 28*; Bupa, *Submission 31*; The Hon Sussan Ley MP, former Minister for Health and Aged Care, 'Turnbull Government to ease pressure on private health insurance premiums', *Media release*, 19 October 2016.

5 The Hon Sussan Ley MP, former Minister for Health and Aged Care, 'Turnbull Government to ease pressure on private health insurance premiums', *Media release*, 19 October 2016.

6 See, for example: Medical Technology Association of Australia, *Submission 2*; CONMED Linvatec Australia, *Submission* 5; Private Healthcare Australia, *Submission* 7; HBF, *Submission 27*; Joint submission from four Australian medical device manufacturers and distributors, *Submission 39*.

1.5 Rising health insurance premiums, coupled with an ageing population and an increase in hospital admissions has sparked concerns that the public health system will be under even greater pressure in the future.

Conduct of the inquiry

1.6 This inquiry was referred by the Senate for inquiry on 21 November 2016, with a reporting date of 30 March 2017.[7] On 23 March 2017, the committee received an extension of time to report until 10 May 2017,[8] and on 10 May 2017, the committee received a further extension to 11 May 2017.[9] Details of the inquiry are available on the committee's website.[10]

1.7 The terms of reference for this inquiry are:

Price regulation associated with the Prostheses List Framework, with particular reference to:

(a) the operation of relevant legislative and regulatory instruments;

(b) opportunities for creating a more competitive basis for the purchase and reimbursement of prostheses;

(c) the role and function of the Prostheses List Advisory Committee and its subcommittees;

(d) the cost of medical devices and prostheses for privately insured patients versus public hospital patients and patients in other countries;

(e) the impact the current Prostheses List Framework has on the affordability of private health insurance in Australia;

(f) the benefits of reforming the reference pricing system with Australian and international benchmarks;

(g) the benefits of any other pricing mechanism arrangements, including but not limited to those adopted by the Pharmaceutical Benefits Scheme, such as:

(i) mandatory price disclosure,

(ii) value-based pricing, and

(iii) reference pricing;

(h) price data and analytics to reveal the extent of, and where costs are being generated within, the supply chain, with a particular focus on the device

7 *Journals of the Senate*, No. 16, 21 November 2016, pp. 497-497.

8 *Journals of the Senate*, No. 34, 23 March 2017, p. 1150.

9 *Journals of the Senate*, No. 40, 10 May 2017, p. 1325.

10 See: http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ProsthesesListFramework.

categories of cardiac, Intra Ocular Lens Systems, hips, knees, spine and trauma;

(i) any interactions between Government decision-making and device manufacturers or stakeholders and their lobbyists;

(j) any implications for prostheses recipients of the National Disability Insurance Scheme transition period; and

(k) other related matters.[11]

1.8 The committee received 45 submissions from a range of individuals and organisations including medical device manufacturers, private health insurers, private hospitals, practitioners, consumer groups and government departments.

1.9 The committee acknowledges those who contributed to the inquiry through submissions or as witnesses. A list of the individuals and organisations who provided submissions to the inquiry is available at Appendix 1.

1.10 Three public hearings were held in Canberra on 15, 16 and 31 March 2017. Transcripts of these hearings are available on the committee's website and a list of witnesses who gave evidence at the public hearings is provided at Appendix 2.

Structure of the report

1.11 This report is divided into five chapters:

- **Chapter 1** provides a background to the committee's inquiry and an overview of the operation of the PL Framework.
- **Chapter 2** examines past reform of the PL, issues and relationships between stakeholders and the effect of the current PL Framework.
- **Chapter 3** examines the current reforms under way.
- **Chapter 4** examines alternative models and opportunities for reform.
- **Chapter 5** concludes the committee's consideration and makes recommendations for further consideration.

Operation of the Prostheses List Framework

What is the Prostheses List

1.12 The PL was introduced by the Australian government in 1985 to regulate the price of prostheses paid by patients with private health insurance and reduce public hospital waiting lists for procedures involving prostheses.[12]

1.13 For the purposes of the PL, a prosthesis is defined as a surgically implantable device such as a cardiac pacemaker, intraocular lenses used in cataract surgery and hip

11 *Journals of the Senate*, No. 16, 21 November 2016, pp. 497-497; See also: http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ProsthesesListFramework.

12 Department of Health, *Submission 38*, p. 8.

or knee joints used in replacement surgeries. The PL does not included external devices such as hearing aids or prosthetic limbs. [13]

1.14 The PL enables surgeons to have access to and chose the optimal prostheses for patients covered by private health insurance. Private hospitals purchase prostheses directly from device manufacturers and often receive rebates or other incentives from manufacturers for buying in bulk or achieving certain volume amounts, commonly referred to as volume discounts. Where a private patient receives treatment in a public hospital, the public hospital is able to access prostheses at a much lower price and invoice the private health insurer for the higher minimum benefit amount on the PL.

1.15 A patient's private health insurer is required by law to pay the minimum benefit amount for any prostheses included on the PL, regardless of the price paid by the hospital for the device. The price of prostheses are passed on to consumers through health insurance premiums and indirectly to government through the private health insurance rebate.

Regulation of the Prostheses List

1.16 Division 72 of the *Private Health Insurance Act 2007* (PHI Act) sets out the PL Framework and provides that private health insurance policies must cover the benefit amount of a prosthesis included on the PL.[14] The Private Health Insurance (Prostheses) Rules set out the listing criteria which must be satisfied in order for a prosthesis to be included on the PL.[15]

1.17 The PL is divided into three parts which are outlined below:

- Part A includes surgically implantable devices and integral single-use aids used to implant the device.
- Part B includes human tissue-based products that are regulated by the Therapeutic Goods Administration (TGA) as 'biologicals'.
- Part C includes devices which do not meet the criteria for Parts A or B and are determined at the Minister's discretion. Currently Part C is limited to insulin infusion pumps, implantable cardiac event recorders and cardiac home/remote monitoring systems.[16]

1.18 As at 1 December 2016, 10 718 individual prostheses were listed on the PL.[17]

1.19 Prostheses included in Parts A and C can be divided into four different tiers: categories, subcategories, groups and subgroups. [18] Firstly, prostheses are organised in a hierarchical structure into the following categories:

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13 Department of Health, *Submission 38*, p. 2.

14 *Private Health Insurance Act 2007*, https://www.legislation.gov.au/Details/C2016C00911 (accessed 3 May 2017).

15 Private Health Insurance (Prostheses) Rules 2017 (No. 1), https://www.legislation.gov.au/Details/F2017C00240 (accessed 3 May 2017).

16 Department of Health, *Submission 38*, pp. 2, 4.

17 Department of Health, *Submission 38*, p. 2.

- Cardiac
- Cardiothoracic
- Ear Nose and Throat
- General Miscellaneous
- Hip
- Knee
- Neurosurgical
- Ophthalmic
- Plastic and reconstructive
- Specialist Orthopaedic
- Spinal
- Urogenital
- Vascular.

1.20 Prostheses are then divided into subcategories based on the essential function of the prosthesis. The devices are subsequently allocated into groups which reflect their specific function and may be further divided into sub groups to differentiate them on the basis of performance.[19]

1.21 Following the *Review of Health Technology Assessment in Australia 2009* (HTA Review) (discussed further in Chapter 3), each grouping of prostheses on the PL has a single minimum benefit level.[20] That is, the amount paid by private health insurers for a particular prostheses is the same amount for each prostheses listed in that group.

New prostheses

1.22 In order for a prosthesis to be included on the PL an application must be made, usually by a medical device sponsor or supplier (i.e. the device manufacturer), which outlines how the device meets the listing criteria for Part A or C and the comparative clinical effectiveness of the device.[21]

1.23 Applications are considered by the Prostheses List Advisory Committee (PLAC) which is made up of experts in clinical practice, health economics, health technology assessment and health consumerism as well as representatives of the Department of Veteran Affairs, the TGA and major stakeholder organisations.[22]

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18 Department of Health, *Submission 38*, p. 4.

19 Department of Health, *Submission 38*, pp. 4-5.

20 Department of Health, *Submission 38*, pp. 4, 10.

21 Department of Health, *Submission 38*, p. 5.

22 Department of Health, *Submission 38*, p. 7.

The PLAC is supported by Clinical Advisory Groups (CAGs), a Panel of Clinical Experts and the Health Economics Sub-Committee (HESC).[23]

1.24 All applications for new prostheses are subject to an administrative assessment by the Department of Health (the department) to ensure that sufficient information has been provided.[24] Applications are also subject to a clinical assessment by appropriate experts who are members of a CAG or Panel of Clinical Experts and provide advice on whether the device satisfies the listing criteria and can demonstrate comparative clinical effectiveness.[25]

1.25 If the prosthesis is a new device and the sponsor proposes that it be included in a new grouping, subgroup or suffix on the PL, the HESC assesses the sponsor's application to determine if the recommended benefit is reasonable and that the proposed benefit amount reflects the demonstrated difference in clinical outcomes between the new prostheses and existing prostheses included on the PL.[26] The HESC also considers advice from clinicians on the comparative clinical effectiveness of the new device and provides their assessment to the PLAC for consideration.[27]

1.26 The PLAC provides advice to the Minister of Health (or the Minister's delegate) who ultimately decides whether a device should be included on the PL.

Administration of the Prostheses List

1.27 The PLAC and the administration of the PL is supported by a secretariat within the Department which includes 12 full time equivalents (FTE's).[28]

1.28 The cost of processing and maintaining the PL is recovered by the department through the payment of fees. Medical device sponsors and suppliers are required to pay a fee to apply for a new listing and to maintain devices on the PL as outlined below:

- $600 to make an application for a new item to be included on the PL;
- $200 to initially list a new prosthesis; and
- $200 payable twice per year to maintain a prosthesis on the PL.[29]

1.29 Currently the department receives approximately $4.4 million per annum in fees.[30]

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23 Department of Health, *Submission 38*, pp. 5-6.

24 Department of Health, *Submission 38*, p. 6.

25 Department of Health, *Submission 38*, p. 6.

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

27 Department of Health, *Submission 38*, p. 6.

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

29 Department of Health, *Submission 38*, p. 2; Private Health Insurance (Prostheses Application and Listing Fee) Rules 2008 (No. 1).

30 Department of Health, *Submission 38*, p. 2.

Size of the industry

1.30 In 2015-16 the private health insurance industry provided $18.9 billion in health insurance benefits, increasing 5.1 per cent from 2014-15.[31] Medibank, Australia's largest private health insurer, spent $5.1 billion on their customer's health care last financial year. Of this, $540 million was on prosthetic devices alone.[32]

1.31 Private health insurance plays a significant role in Australia's healthcare system. As at 30 September 2016, 46.8 per cent of Australians were covered by hospital treatment policies and 55.6 per cent had a form of general treatment cover.[33] Two in every five hospital admissions are funded by private health insurance representing 33 per cent of all days of hospitalisation in Australia.[34] In addition, approximately two thirds of elective surgeries are performed in private hospitals which reduce waiting times for elective surgeries in public hospitals.[35]

1.32 While private health insurance reduces pressure on the public hospital system, the industry is also subsidised by the Australian government through the income-tested Private Health Insurance Rebate. The rebate is expected to cost the Government $6.4 billion in 2017-18.[36]

1.33 The committee heard throughout the inquiry that is not only the cost of prostheses which places pressure on private health insurance premiums but also the increase in utilisation of prostheses, hospital admissions and Australia's ageing population. While these other factors are important considerations for the future of Australia's healthcare policy, the focus of this inquiry is on the PL Framework.

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31 Department of Health, *Submission 38,* p. 2.

32 Medibank, *Submission 14*, p. 3.

33 Department of Health, *Submission 38,* p. 2.

34 Medibank, *Submission 14*, p. 3.

35 Medibank, *Submission 14*, p. 3.

36 Department of Health, *Submission 38,* p. 1.