Price regulation associated with the Prostheses List Framework

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

Submission by Dr Janet L Wale, independent health consumer advocate

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The terms of reference:

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 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.

Submissions should be received by **30 January 2017**. The reporting date is **30 March 2017**.

I have prepared my submission as an experienced consumer advocate in Australia since the year 2000. I am happy to discuss this submission further.

About myself

I have state, national and international experience in my capacity as a consumer representative I recently completed my term as chair of the Health Technology Assessment International (HTAi) Patients and Citizens Involvement in HTA Interest Groups, and have been the consumer coordinator of the Consumer Network of the Cochrane Collaboration supporting evidence based health care (http://www.cochrane.org/). I was the consumer representative on the Prostheses List Advisory Committee (PLAC) for 4 years and am on the Advisory Committee of the Australian Orthopaedic

Association National Joint Replacement Registry. I continue to works coproductively with clinicians on two PLAC Clinical Advisory Groups and have experience on clinical committees for the MBS Review Taskforce.

Points to make

I wish to address some but not all of the points covered in the terms of reference for the present Senate Committee. A number of these points are closely inter-related (points c to e). I touch on a value framework and pricing, and refer under point k to the related matter of how the Prostheses List Advisory Committee (PLAC) defines 'a prosthesis', and therefore its scope.

Greater transparency and consistency required

My overarching request is for greater transparency about, and acknowledgement of, the areas covered by the work of Prostheses List Advisory Committee (PLAC) and its sub-committees. It is only with this greater knowledge and understanding by the Australian public that we can start to address the impact on healthcare costs, in this case within the private healthcare system.

The work of PLAC certainly needs to be assessed in terms of the role it plays in optimising health outcomes for Australians through the private health system, and ultimately through public hospitals as well. The Prostheses List provides just one important component for the care of patients who require a prosthesis or medical device to improve their health outcomes. Theatre costs, associated care and rehabilitation are some of the other elements of care.

It needs to be pointed out that the Prostheses List, and therefore the work of PLAC, impacts on devices in public hospitals in the absence of a national body that applies reimbursement decisions for medical devices in public hospitals beyond MSAC and the TGA regulatory processes. No equivalent system to the provision of medications through the Pharmaceutical Benefits Scheme applies for medical devices, yet medical devices can have as important a role in managing health outcomes.

Definition of a prosthesis affecting equity of services

It would seem (from Google) that the definition of a prosthesis, or medical device, can be problematic. The current definition used by PLAC is particularly troublesome. Although it is in the PLAC Reform Work Plan to look at (http://www.health.gov.au/internet/main/publishing.nsf/Content/health-privatehealth-prostheseslist.htm) this is too important an issue not to be addressed by the Senate Committee. It is time that we work to develop consensus on an easily understood, publicly defensible definition. The reimbursement mechanisms for medical devices in general need to be clearly defined and transparent for Australian consumers.

Medical devices need to be treated equitably. Some items are required to go through MSAC. Some items such as external bone or spine fixators and glucose pumps are made available on the Prostheses List, by exception. Some items are simply not available through the private health system, reducing the quality of care within private health.

The present definition that PLAC applies may 'save' money for private hospitals but it is not supportive of an open transparent approval system for medical devices within Private Health. Nor does it lead to equity of services. Some items may be negotiated to be added to theatre lists but this will be limited and vary from hospital to hospital. Other items are not uniformly made available for use in private hospitals despite a strong evidence base for their use, for example cardiac ablation catheters; clot removal catheters; test electrostimulators for the brain (such as for treatment of Parkinsons, epilepsy). What this means is that services provided are not equitable and affect those devices available for use in private health patients depending on whether they are in public or private hospitals.

Room for beneficial innovative medical devices while protecting the wellbeing of patients
With innovations in software and monitoring devices - that could make dramatic changes to adherence and compliance to treatment, monitoring of health state and improved health outcomes - come added challenges to the definition being applied to prostheses within our current system. Some of these devices may be relatively low cost and have good potential to improve health outcomes. It would be good to be able to measure this – as with the use of large datasets and electronic health records.

I understand through my work with the National Joint Replacement Registry and in HTAi that innovation can also contribute to the spiralling costs of health care. Often this is without any clear benefit for patients. Collection of data in registries and large datasets is required to provide us with a firm evidence base for reimbursement.

I was one of a number of consumer representatives who spent some time talking with the previous Chief Executive Officer of Private Healthcare Australia about the lack of added benefit to patients with newer hip and knee prostheses over proven prostheses, as well as the importance of infection rates in hospitals and associated care. Where is the mechanism within our health system to make these discussions more public?

A value framework – both clinical and economic
The affordability of medical devices for Australians brings with it the challenge of managing the interface between government, private hospital industry and the medical devices industry. Both of the latter are competitive commercial environments.

Background to the Prostheses List
The Prostheses List, although not perfect, is a negotiated value framework for medical devices, from screws and wires through to complex devices. It took years of skilfully negotiated pricing with strong clinical expertise from the relevant clinicians grouped by speciality in Clinical Advisory Groups. A purpose of these clinical groups was to best categorise the many items on the Prostheses List and working on the basis of clinical benefit.

The importance of value
Innovation is a driving force in today's world, and with it comes associated increases in cost. Innovation for the sake of innovation does not always reap benefits to the end users, the patients. It

is important that improved health outcomes are shown for patients and ultimately the population in general.
As with the MBS Review Taskforce, clinical and consumer input is required to understand in practical terms changes being made to services and technologies, how these are being used within the system, and to ensure both clinical and financial value. In the case of medical devices, the National Joint Replacement Registry has been vital in leading the way to show how registries and large datasets can be used to provide clinical evidence on the value of innovation within the Australian healthcare system, where the majority of joint replacement takes place within the Private Health system.

We need to develop more sophisticated approaches to the measurement of outcomes using real world data, patient reported outcomes and an assessment of wider societal benefit. Developments in information technology may assist us in gathering the evidence of benefit required to inform reimbursement decision making – both in other countries and nationally. This information gathering, with the full cooperation of sponsoring medical device companies, needs to be balanced against transparency about and accessibility of new medical devices/prostheses.

Pricing
I argue that the negotiating power of state health systems and individual hospitals, both private and public, within the market place is a key factor in the differences in costs of medical devices.
I query whether the private health system can apply this same pressure, inclusive of all the additional items that add costs to the devices if billed separately - such as extra screws, wired, bone cements, which *are* implanted and *do* stay in the body (as per the prosthesis definition).

It is important that pricing is based on real data, that there is an awareness of what other health systems are paying for the same devices. The literature shows that with reference pricing those who seek the lowest prices wait the longest time for access to the technologies. This may not therefore translate to benefits to patients and may contribute to some longer term costs.

Pricing regulation associated with the Prostheses List Framework is not simply an economist's decision. The wellbeing of patients and the healthcare system with all its components is a key consideration. The public need to be given the opportunity to understand and be involved in these decisions.

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