SPINE SOCIETY OF AUSTRALIA

Department of Health
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By email: prosthesesreform@health.gov.au

15 February 2021

Dear Sir / Madam

Spine Society of Australia
Prosthesis List reform - Stakeholder consultation
Consultation Paper: Options for reforms and improvements to the Prostheses List

The Spine Society of Australia (SSA) appreciates the opportunity to provide comment and information to the **Department of Health (DOH)** on the **Consultation Paper: Options for reforms and improvements to the Prostheses List (the Consultation Paper)**. The DOH has recognised that the proposed reform options were developed with the assistance of the **Revised Benefit Setting and Review Framework Industry Working Group (BSRIWG)** and the BSRIWG report that was published on 16 December 2019. The review did not include any clinicians or clinician representative bodies in the BSRIWG.

Our society is well placed to provide input into this consultative process, as our membership encompasses both clinicians and researchers who share the common goal of the understanding and management of disorders of the spine. Orthopaedic and neurosurgical spine surgeons make up the bulk of our membership and rely on access to the prostheses, devices and products listed on the PL to provide their privately insured patients with the highest possible standard of medical care. The SSA submission is focused on this subspeciality, while we acknowledge that our interventional pain physician members will also be contributing through the Australian and New Zealand College of Anaesthetists Faculty of Pain Medicine and the Neuromodulation Society of Australia and New Zealand.

Australia's unique health care system, combining universal health care through Medicare and the public hospital system with private health insurance, is world leading. A review of one part of that system must necessarily consider any impacts on the other sector. We anticipate that our submissions will assist the DOH with the further development of policy that will secure the continued health of both the private and public sectors.

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1. Reform of the Prosthesis List

The **Prosthesis List (PL)** is the subject of the current consultation and has come under intense public scrutiny in the last few years at the behest of the **private health insurers (PHI)** and the **Private Health Association (PHA)**. **The level of scrutiny is disproportionate to impost on PHIs, forming only ~11% of the costs of private health care.** The PL has gone through multiple rounds of reform since its inception in 1985 and was previous deregulated at the behest of the PHIs in 1999. Ultimately, the rapid escalation of prosthesis prices resulted in the reintroduction of regulation in 2005. This led to the development of arrangements that would ensure independent clinical advice was integral to determining the clinical effectiveness of a device and the benefit levels for new prostheses. These roles are now performed by the **Prostheses List Advisory Committee (PLAC)** and its subcommittees, such as the **Clinical Advisory Groups (CAGs**) and Panels of Clinical Experts.

Since the introduction of these reforms, while the volume of implanted devices has more than doubled, the average benefit paid per device has fluctuated very little.[1] There has been no continued exponential increase in the average cost of a prosthesis on the PL but it has been argued the initial prices were set artificially high, especially when compared with the cost of prothesis in the public sector. **The Medical Technology Association of Australia (MTAA)**, since its 2017 agreement with the Government **(the MTAA Agreement)**, has worked constructively with the Government to rebalance the cost of medical devices on the PL. **It is noted that in the MTAA agreement, that the Government, *recognises the role of the Prostheses List in supporting the value proposition of private healthcare to Australian consumers***, is due to expire on 31 January 2022. These reforms to date have delivered savings of in excess of $1.1 billion over four years.

Any reform of the PL must start with the key consideration of who is the 'consumer' of the medical devices listed on the PL. It is not the hospital nor the clinician, it is the Australian undertaking an episode of private hospital treatment under their private health insurance. Australians choose to take out PHI not for altruistic purposes (ie to unburden the public system) but for what they believe to be the personal benefits of being privately insured. These perceived benefits include the desire to choose their doctor, to have shorter waiting times, and the belief they will receive a higher standard of care.

The patient/doctor relationship is at the core of the Australian health system and is underpinned and secured through the ethical and professional obligations of the doctor and the legal duties they owe to the patient. Any changes to the PL must, first, recognise the importance of this relationship and, secondly, must not have the potential to undermine it. Further, the risk of liability of the treating practitioner must not be increased because of the changes.

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1 https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/ProsthesesListFramework/Report/c04

The SSA recognises that part of the value proposition of PHI for the consumer is the lowest possible premiums and the least potential for 'out of pocket' expenses. The SSA will continue to work with the Government on changes to the PL that support these outcomes.

Any reform of the PL must involve clinicians at each step. It is noted that clinicians have been presented with two options for reform that will fundamentally affect their relationship with private patients without having participated in the BSRIWG review or report.

2. The Consultation Paper – Options 1 & 2

The SSA does not support Option 1 nor Option 2 as outlined in the Consultation Paper but is committed to working with the Government and the DOH in continuing to reform the PL.

a. Option 1 – Introduction of DRG funding for prostheses

The SSA is fundamentally opposed to the introduction of a Diagnosis Related Groups (DRGs) model of protheses funding in the private health sector (Option 1). It is noted that this proposal was developed by BSRIWG and the DOH without any input from clinicians in private practice, particularly spine surgeons.

As discussed below, the SSA supports the rationalisation of the device groupings on the PL but grouping services under a small number of DRGs relating to spine surgery is unworkable.

The number of DRG s for spine surgery can in no way account for the diversity of spine surgery. In the case of the very complex spine surgery, such as scoliosis surgery, the procedures range from standalone anterior fusion over 4-5 motion segments to combined anterior and posterior fusion over 15+ motion segments. Both would fall under the DRG "spinal fusion for deformity." But the difference in prosthetic costs between both ends of the spectrum of scoliosis correction reaching over $75,000. Even if current prosthesis prices were halved, this would still equate to a difference of over $30,000 in prosthesis costs for the range of surgery performed under one DRG.

Even within the simpler example of two level spinal fusion the variability of diagnosis, approach, technique and preferred prostheses, human tissue products, navigation and general category items would make the administration of prosthesis remuneration based in DRG , a lottery for private hospitals.

In relation to a DRG for two level spinal fusion:

- A two level spinal fusion is undertaken for many different pathologies, including degenerative disease, tumour, trauma, and infection.
- Each pathology involves differing surgical techniques and prostheses dependent on multiple factors, including individual patient demographics, the extent of the disease, the surgeon's expertise with particular approaches to the spine, and the intra-operative findings.

- There are multiple surgical approaches to the spine to treat two level disease, each involving different levels of complexity in the use of spinal prostheses. In order of complexity, a two level fusion can involve:
    - Un-instrumented fusion, with no instrumentation but with the use of bone extenders/enhancers.
    - Uni-lateral **posterior spinal fusion (PSF)**, with pedicle screws and rod instrumentation.
    - Bilateral PSF, with pedicle screws and rods bilaterally.
    - PSF with single level interbody cage, plus screws and rods bilaterally.
    - PSF with two interbody cages, plus screws and rods bilaterally
    - **Anterior lumbar interbody fusion (ALIF)**, with two cages and two plates and screws.
    - ALIF, with two cages and two plates and screws, supplemented with posterior pedicle screws and rods.
    - A vertebrectomy, with a vertebrectomy cage, supplemented with posterior pedicle screws and rods.

The prostheses requirements noted above have not included the surgeon's preference for general category items and human tissue items, required to complete the procedure.

No median DRG pricing model can account for all the complexity of spinal pathology and clinical decision making in spinal procedures. Under any median DRG model, approximately half of procedures will not have adequate remuneration the prostheses required. This would lead to "cherry-picking" by private hospitals. Efforts to minimize the funding disparities within each DRG would require a massive expansion of the number of DRGs, making any claim to simplification illusory, and having the preserve outcome of an exponential rise in costs relating to coding, claiming, and the management of the DRGs.

Rather than DRGs, the SSA supports the use of the current spinal surgery MBS item numbers, describing specific surgical procedures, being used to assist in the assessing of the medical devices and general use items used in association with the MBS items. The SSA is happy to work with the DOH further in this area.

It is suggested by the DOH, under *anticipated stakeholder impact*, that *consumers and clinicians should be unaffected by these changes provided there continues to be a reasonable choice of devices*. The two level fusion example demonstrates how this will not be the case. Grouping of spinal fusion procedures into DRGs will inevitably result in surgeon choice and patient care being compromised. The prostheses required for complex spinal procedures will not be covered by the DRG price and private hospitals will not be able to absorb the cost and remain viable. This will inevitably result in an exodus of complex spinal procedures to the public hospital system. Due to the purchasing power of large public institutions, they will be able to offer a wider range of prostheses and procedures than the private hospitals under a DRG system.

Further, the system that will necessarily need to be put in place by the private hospitals to control spending under a DRG system, will serve to erode the patient/doctor relationship. The hospital will ultimately mandate a limited range of prostheses (and thereby procedures) available to the surgeon, should he choose to admit his patient to that institution. If the surgeon submits and abandons their preferred technique and prostheses (which they have considerable experience with and have achieved consistently good clinical outcomes) for what they consider to be a less optimal technique and combination of device, they alone remain legally responsible to their patient for that decision.

Post DRG administrative processes in private hospitals will be complex and will have the result of delaying a privately insured spinal patient's access to care. Again, there may be the perverse result that complex spinal surgery can more readily be accessed in the public system than the private. Waiting lists for surgery in the private system will become a norm, as their treating surgeons navigate the bureaucracy surrounding access to care.

In the case of spine surgery and the PL, it has been clearly demonstrated that a DRG system will undermine the independence of the surgeon in the patient/doctor relationship, reduce the surgeon's choice of procedure and prostheses, limit the patients' access to care in the private system, and will create unreasonable delays in undergoing treatment. **The introduction of the DRG system for prosthesis funding will not achieve the Government's intended results for the review of the PL. It will have the perverse result of undermining the consumer's value proposition for retaining their private health cover and see an exodus of Australians out of private cover and into the public system.**

The introduction of DRG based funding for prostheses is the first step towards the introduction of managed care in Australia. This is clearly anticipated by the DOH, who suggest the PL reform *could be a steppingstone to the private sector wholly moving to a DRG payment system.*

The SSA opposes the introduction of a DRG based managed care system in Australia. The SSA notes that Australians value the current public/private mix of the Australian health system and are well informed about the international patient experience in a managed care health system. The SSA believes that privately insured Australians would not be prepared to continue paying a premium for their healthcare via PHI under such a system.

b. Option 2 – Extensive Changes to the PL

The SSA does not agree with the proposed changes to the PL list as outlined under Option 2. Whilst the SSA supports the need for a review of the way prostheses are evaluated and funded, we believe that there needs to be considerable consultation with the medical and surgical professional organisations before a final model in decided.

The 'minimum redesign' suggested in Option 2 contains some of the fundamental elements of Option 1 and the SSA refers the DOH to the submissions under Option 1 in that regard.

The SSA supports well structured post market reviews and monitoring of protheses usage and outcomes. This needs to be based on high evidence levels and clinicians need to be part of the leadership of the new system from its design to implementation. Well supported and government funded device registries are integral to the success of this system of surveillance. Patient Reported Outcome Measures (PROMs) need to form an important component of these reviews. See further below.

The proposed "development of a compliance programs to enable proper scrutiny of disputed and anomalous claims" is not fleshed out and echoes the submission made by the PHA. These will comprise retrospective reviews of clinical decision making led by PHIs and private hospitals. Clinical decision making in the private hospital setting is already addressed by mandatory morbidity & mortality reviews, through the surgeon's mandatory **Royal Australasian College of Surgeons (RACS)** annual peer reviewed surgical audit, and by other regulatory means. **The PHIs, under this option, are seeking to "reverse engineer" managed care. The outcomes for clinicians and their patients will be the same as discussed under Option 1.**

The SSA notes that the individual surgeon in private practice will not have the ability to manage the increasing burden of regulation, review, and compliance under this new model in addition to their current obligations. The models being proposed are akin to what is used in the managed care system in the USA, where surgeons practice in large group practices or as employees of the hospital where they work. In those workplaces, entire departments of administrative and support staff handle coding and compliance issues. Further, surgeons are generally supported in private practice by a team of clinicians including nurse practitioners, physician assistants, postgraduate fellows, and other allied health professionals within the same institution. In Australia, the surgeon in private practice business model is predominantly sole practice with a few small group practices in some sub-specialties. Average support staff per surgeon is around 2.5.[2] Based on the administrative burdens being suggested, surgeons will have no choice but to employ more staff and pay for the services of external experts. Any increase in administrative burdens on a surgeon's practice will inevitably result in larger 'out of pocket' expenses in relation to surgeon fees.

[2] The Australian Benchmark Report, Surgeons: General 2016, Benchmarking Australia.com.au

3. The SSAs position and recommendations regarding reform of the PL:

a. The role of the PLAC and CAGs should be retained and enhanced in any PL reforms.

b. There is potential for a closer relationship between CAGs and the Therapeutic Goods Association (TGA) and its Australian Register of Therapeutic Goods (ARTG), with respect to determining safety and efficacy.

c. The SSA broadly supports the introduction of the three tiered pathway as outline by BSRIWG. It is understood that this is in the process of being trailed and has yet to be finalised. However, the final system to be implemented needs to ensure that the systems do not result in a perverse system whereby it is much more difficult for patients to access prostheses in private than in the public system.

d. The SSA broadly supports the identification of relevant MBS items with prostheses listed on the PL. However, both proposals put forward by the DOH have monitoring and scrutiny through compliance programs, apparently designed to provide PHIs the ability to question the clinical decision of the treating physician.

Clinician scrutiny is at record highs in Australia, through a myriad of bodies from hospital morbidity & mortality committees through to investigations by the medical board. The PHA has made much of late of the **so called 'off label' usage of medical devices on the PL**. The SSA notes that the **TGA confirms that there is no such legal concept in Australia and the decision to use a device outside its ARTG registered use or indication is to be dealt with in the confines of the patient/doctor relationship, with the patient being informed and *the patient and health professional will need to make a joint decision on treatment options***.[3] An example of such a situation is when a device is registered with an indication for use in a particular population (eg 18-60 year old's) based on the studies performed on the device and the treating surgeon determines it is appropriate for the treatment of their individual patient outside the cohort (eg a 65 year old). **The SSA does not support any encroachment on their therapeutic relationship through the regulation of what is specifically 'on' and 'off label' in Australia. Australian medical practitioners are more regulated and scrutinised than any other profession in Australia and the SSA does not support this further layer of scrutiny through PL based clinician compliance programs.**

e. The SSA supports some changes to what is considered to be a 'prothesis' for the purposes of the PL, in keeping with technological advancements, by changing the definition so that it no longer requires the device to be implantable.

3 https://www.tga.gov.au/early-warning-system-health-professional-questions-and-answers

f. **The SSA supports the removal of the general use medical devices and consumables, on the condition that alternative means of funding by PHIs are mandated in advance of their removal. There is potential for the development of a separate list of general use items**.

If the PHA proposal is accepted, there is predicted to be in excess of $250million of immediate cost shifting to the private hospitals and, without intervention, patient care would undoubtedly be compromised in the intervening years of renegotiating the contracts between PHIs and hospitals. In this situation, access to these general items would be dependent on the size of the hospital organisation (bargaining power) admitting the patient and leave smaller hospitals unable to compete. By the nature of their roles as **visiting medical officers (VMOs)** in private hospitals, clinicians are often not made aware of the comparative costs of the general/disposable products they use. Simple education techniques (such as displaying the cost of items on their packaging in theatre) could assist with clinical decision making when the only point of difference between products is price.

g. **The SSA supports the rationalisation of the number of devices on the PL, which will be substantially achieved by the eventual removal of the general category items. It could also be assisted through reforming the pricing mechanism that allows the problems relating to the 'uncoupling' of devices on the list to be solved.**

h. **The SSA supports consideration of further models of pricing that would lead to a smaller or no gap between private and public pricing of prostheses. However, the SSA points out that, to achieved this, and maintain a viable medical technology industry in Australia, there may need to be an increase in public hospital prosthesis pricing.**

The SSA notes that an implant price does not only pay for the cost of an individual device (and its research and development) but also for the supply and provision of the device, provision of associated instrumentation and company support for its stocking, handling and use. In spinal procedures, the device companies also provide other services (such as navigation and interoperative neural monitoring) at no additional cost.

While the SSA is not privy to all the levers that determine public and private hospital pricing, it acknowledges the proposition is not as simple as reducing private prosthesis prices to public levels. Prices are undoubtedly able to be kept as low as possible in the public system through a competitive tendering process that is heavily reliant on volume. From the view of the clinician in the public setting, there has been some costs associated with the public pricing system:

- **The tendering process with reduced prices has had the effect of limiting availability of instrumentation. Instrumentation sets are a high cost components and multiple sets are required to ensure quick theatre turnover time. Private hospitals viability could not be sustained based on the through put of public hospital theatres.**

- The tendering is also often associated with the reduction in the volume and expertise of clinical support services, with consequent costs reflected back to the hospital in the form of increased storage and labour costs for implant handling and restocking.

- With more limited selection of prostheses, there may be substantial cost differences with respect to handling and sterilisation costs (number of implants involved and associated equipment)

There is no doubt that the discounted pricing in the public system is currently being partially recovered through the private sector. There is benefit to the implant manufacturer by having surgeons and surgical trainees exposed to and becoming familiar with devices in the public sector in the hope that that familiarity will increase subsequent usage in the private sector, and thereby assisting in offsetting any losses. **Should significant reductions be made to the rates of private reimbursement, there will be a price point at which prices in the public sector will inevitably start to rise.**

It needs also to be acknowledged that the device industry makes significant funding contributions to both the public and private sectors in the form of funding post-graduate fellowship positions that are heavily relied upon by public hospital departments, device registries, and specialist and trainee education programs (and not limited to device industry style meetings).

i. **The SSA also supports consideration of international referencing but this, again, is a complex area in view of the wide range of differing health systems globally. Any change in pricing on the basis of reference pricing would require significant investment of time and expertise and would not meet the DOHs goal of a role out post 21 January 2022 in our view.**

j. **The SSA supports the continued use of medical device registries as important tools in determining the safety and efficacy of prostheses and informing clinicians and decision makers in relation to the performance of a device compared with other devices treating the same pathology. The role of registries need to be expanded beyond revision statistics to include PROMs**. While the **Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)** and the **National Cardiac Registry (NCR)**, and others, receive federal government funding, the SSAs **Spine Australian Spine Registry (ASR)** does not. **A roll out of secure government- funding of national device registries should form part of the overall strategy for managing the PL and medical devices in Australia as evidenced by the comparable Swedish system.**

4. The Consultation Paper Questions - Improved Definition of Purpose and Scope

What, if any, general use products should continue to be funded though the PL and why?

This question has been addressed in the SSAs position statement.

Should there be an "exceptional circumstances" list (akin to the current Part C)? If so, what types of products should be listed and why?

The SSA supports the creation of a separate list for general use items but not an "exceptional circumstances" list for the reasons outlined in the SSAs position statement.

How should general use items be transitioned to other payment arrangements in a phased manner? What time period and should some items continue to be listed for longer than others? If so why?

This question has been addressed in the SSAs position statement.

5. The Consultation Paper Questions - OPTION 1: Consolidate the Prostheses List using the Diagnosis Related Groups (DRGs) model and set benefits with reference to the prostheses price components of relevant DRGs, with administration moved to the Independent Hospital Pricing Authority (IHPA).

Should the public/private gap be closed completely or instead allow for relativity that favours the private sector? If so why?

The SSAs position on pricing under the PL is discussed above.

What evidence is there that choice of prostheses in the public sector is more limited than the private hospital sector? Is there any evidence of difference in outcomes in the public and private settings?

In spinal surgery not all prostheses on the PL are available in the public system. While some prostheses are available earlier than in the private system, the tendering system and price point restrict the choices available to treating spine surgeons.

In relation to the differences in outcomes between the private and public system, this is an area that has only been the subject of low quality papers. It is important for any long term consideration of this question that well constructed publicly funded prospective comparator trials are conducted. Current registry data, while helpful, is simply meta data and caution needs to be used in drawing conclusions from it without further evidence. The important role of registries is discussed above.

While revision rates of prostheses may at some price points be comparable, it does not account for all the differences (and confounders) when comparing the use of prostheses in the public and private systems. There are important differences between public and private care that are not evident in revision rates in metadata. What is considered a good clinical outcome from surgery will differ between the systems, thereby affecting the revision rates between the systems. Further, the ability of a postoperative patient to re-enter the system for further care varies greatly between public and private.

How should concerns about maintaining choice be addressed?
The SSA position on this is addressed in the body of this submission.

What market distortions would be continued or created by this proposal and how can they be addressed?

The SSA position on this is addressed in the body of this submission.

6. The Consultation Paper Questions - OPTION 2: Consolidate and redesign the Prostheses List with extensive changes to pre- and post-listing assessment and benefit setting processes, with administration of benefit setting supported by the Department of Health.

What advantages or disadvantages does option two have over option one?

The SSA does not agree with either options for the reasons stated in the body of the submission.

What groups structure should be used and why? Examples include grouping by episode of care, procedure or device?

The SSA position on this is addressed in the body of this submission.

Would it be possible to use IHPA's DRG grouping structure as part of reforming the PL under this option?

The SSA position on this is addressed in the body of this submission.

If benefits are set through commercial tenders (for existing products and categories), how frequently should those tenders occur?

The SSAs position on tendering is addressed in the body of this submission.

If benefits are set through reference pricing, should this include public hospital prices and international prices? Which countries should be referenced, how and why? For public hospitals, how would reference pricing be supported outside the IHPA framework, and should this include averaging?

The SSAs position on this addressed in the body of this submission.

How should compliance be supported to ensure companies accurately identify referenced prices?

The SSAs position on this is addressed in the body of this submission.

7. Conclusion

The SSA supports the Government's review of the PL and is committed to assisting in this process to find outcomes that best serve the Australian consumer of private health care, while at the same time preserving the inviolability of the patient/doctor relationship in clinical decision making.

To date, input from clinicians and their representative bodies have been left out of the review process and that has led to development of options for reform that will not work in the Australian private healthcare sector. A DRG based model for the reform of the PL is unworkable in the Australian private health care system and will result in perverse outcomes, undermining the value proposition of PHI, an increased number of Australians dropping their PHI, and an increased demand on the public healthcare system.

The SSA also believes that the reform of the PL brings new opportunities for the Government to undertake initiatives that will support the ongoing surveillance of prostheses use in Australian through the expansion of government funding of device registries to a level where most medical devices used in Australia undergo formal long term post market surveillance, with the introduction of PROMS to the registry system. Such an initiative would, ultimately, represent a small figure on the ledger balancing the costs of and savings from the reform of the PL. The SSAs Australian Spine Registry would be well placed to provide this surveillance, given secure funding arrangements.

The real world practice of spine surgery provides clear evidence that any reform of the PL needs to be managed carefully, that the DRG system of prosthesis reimbursement is unworkable, and that PL reforms must be developed in partnership with all stakeholders, including clinicians, and with less haste.

The SSA looks forward to further communications from the DOH about the PL reform and stands ready to assist where it can. Please do not hesitate to contact me should you wish to discuss any aspect of our submission.

Yours sincerely

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