Private Healthcare Australia
Better Cover. Better Access. Better Care.

PHA Evaluation of the Prescribed List Reforms

May 2025

Contact:

Ben Harris – Director Policy and Research
0418 110 863
ben.harris@pha.org.au

About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have 22 registered health funds throughout Australia as members and collectively represent 98% of people covered by private health insurance. PHA member funds provide healthcare benefits for more than 15 million Australians, so our focus remains squarely on the need for a strong, viable, high-quality and efficient hospital sector for these members.

Introduction

The Prescribed List of Medical Devices and Human Tissue Products (PL) reforms have failed to provide savings to Australian consumers and taxpayers. Since the introduction of the reforms on 1 July 2022, the average cost per consumer for medical devices has increased from $190 to $197. This is despite cost being the most important issue facing private health insurance for consumers. Market research repeatedly shows that affordability is top of mind for consumers when it comes to health care. Yet the PL is one of the few remaining systems in the world that regulates prices for surgical implants and supplies on a fee-per-item basis. It is inflationary because prices for many items have been fixed at 30–100% more in Australia than in the public system, or global benchmarks, and there are no regulated controls on volume. These inflated benefits have led to a 'shadow economy' of financial rebates and other benefits paid to doctors and hospitals by multinational medical device suppliers to secure continuing sales and increase profits. This is despite a lack of evidence suggesting quality of patient care is enhanced by these high prices or the volume of devices used.

The cost of medical devices in Australia is the largest contributing factor to health insurance premium increases. In 2024, premiums increased on average by 3.03%, yet medical device spend for health funds increased by 3.7%. In fact, over the past five years, the number of medical devices funded by health insurers has grown by 15.3% to an annual record high of 3.735 million items in the 12 months to December 2024. This surge in device volume is totally out of proportion with only a 5.4% increase in hospital treatment medical services, and a 9.1% increase in hospital episodes funded by health insurers over the past five years. The government must do more to maximise public value for Australians as the PL reforms currently under evaluation are failing to make a difference to consumer costs.

Response to questions

1. Overall, what is your view on how the reforms have progressed and how the Department is engaging with stakeholders?

The PL reform process has been too slow, mainly due to the deliberate efforts of certain stakeholders with vested interests – medical device companies and private hospitals – to delay the process so they can continue receiving high prices, rebates and kickbacks under the status quo. This has prevented considerable savings that could have helped improve the cost effectiveness of private health insurance for the 15 million Australians who are choosing to invest in their own healthcare via health insurance.

The Memorandum of Understanding (MoU) between the previous Minister and the Medical Technology Association of Australia (MTAA) was developed without input from other key stakeholders. The Department has advised,

> "in the view of the Department, [the MoU] predominantly benefitted industry rather than providing a negotiated balance of benefits to industry and the Australian community/government." (FoI 4046)

Despite the MoU predominantly benefitting industry, each of the changes made to the implementation of the MoU has further benefitted he medical devices industry at the expense of consumers and taxpayers.

This includes key backdowns such as the decisions to return general use items to the PL, not implementing the promised price cuts to cardiac implantable electronic devices (CIEDs), and abandoning the regrouping of the PL based on clinical utility rather than device characteristics. Each of these decisions have reduced the benefits of PL reform for consumers and taxpayers making them poor public policy choices.

The decision to return general use items (GUI) to the PL through Part D was incredibly disappointing as it enabled waste and abuse in the system to continue. Private health insurers are committed to funding devices that add value and are critical to surgery, which occurs daily under other consumable agreements. But listing items on Part D without restrictions facilitates low value care, allows devices to be used in contravention of the sponsors' instructions and protects rebate agreements between device companies and private hospitals to the detriment of Australian consumers. Further, the department has not progressed consumer protection measures suggested by PHA, and left incorrect listings in the PL.

The delay in cardiac implantable electronic device (CIED) price reductions has cost consumers over $100 million in foregone savings. The department made representations to funds it would fully implement the savings, including publishing data suggesting it would lead to more than $300 million in savings over the course of the MoU term. This decision was subsequently reversed by the department, which is now failing to implement the recommendations of the Medical Services Advisory Committee to reduce prices. Each week of delay is costing consumers more than $1 million.

Health insurers have provided the department with evidence of abuse in a number of areas of the PL, notably in relation to biomodels and guides. Among the examples highlighted includes cases where spend has exceeded $50,000 for plastic models.

In further examples of not accepting independent advice that would have benefitted consumers, the department did not accept the recommendations to limit the use of surgical guides and biomodels to complex cranio-maxillofacial (CMF) procedures. This is another example where the department has prioritised industry interests over consumers an taxpayers.

The department's engagement with health funds has mostly been open and transparent, which has been appreciated. However, the department has steadfastly refused to provide data on the costs to consumers and taxpayers of policy changes, which is disappointing. Estimates of savings foregone from delays to CIED price changes, for example, have not been forthcoming.

2. What is your view on the benefit reductions made to devices on the PL?

The benefit reductions made to devices on the PL have been in line with the MoU with the obvious exception of CIEDs. PHA would welcome the inclusion of discussion about the savings foregone for consumers in relation to these delays in the evaluation report.

Overall, savings from PL reforms have not emerged as expected. Australian Prudential Regulation Authority (APRA) data shows the total cost of PL items continues to increase. In the past 12 months, APRA data shows PL cycle device spend has grown from more than $2.358 million to $2.446 million (3.7% increase). Claiming savings in the interim evaluation report when spending had increased was disingenuous, and PHA would be very disappointed if Nous repeated this claim in the next report given the data available.

APRA figures show spending on medical devices for the calendar year 2024 was the highest on record – $2,445,763,470. This is partly due to significant increases in the number of hospital episodes, which reached a record 5,117,834 in 2024.

However, we are now finally starting to see some savings occur from medical device pricing reforms year on year for the cost of medical devices per episode, as this covers both cost and volume. In 2024, this has declined from an average $480 to an average $478 per episode, which is saving health funds around $13 million. This saving was accounted for in the last premium round and has been passed on to health fund members.

Another useful measure is how much consumers are paying for medical devices through their premiums. In the year to June 2022, the average cost of medical devices per insured person was $190. In the 2024 calendar year, the average cost per insured person was $197.

Claims that medical device savings should contribute to lower premiums are unsustainable given consumers are paying more for medical devices now than before the MoU commenced.

3. What is your view on how reductions to cardiac implantable electronic devices (CIEDs) have been addressed?

The decision to defer benefit reductions on CIEDs was incredibly disappointing, has led to lower-than-expected cost savings and postponed the reduction to the device component of CIED benefits.

As early as 2016, through Senate investigations into price regulation associated with the PL, it was clear that pacemakers and implantable cardioverter-defibrillators (ICD) on the PL were at multiples of the price of the same devices on the public market and according to global benchmarks. Yet against multiple data sources – including references to 10 other comparable health systems – the reforms were delayed by 12 months after the device industry claimed more work needed to be done to determine the reasonable cost of technical support services being provided for the life of devices.

When these services were subsequently probed by the Cardiac Industry Working Group in 2018-20, the costs were found to be minimal. The review found the average involvement from a CIED technician for private patients was 1.4 interactions per year. These were almost exclusively annual device checks when clinicians were already scheduled for routine surgeries, so they were already at

the hospital when these appointments took place and were seeing around six patients an hour. On this basis, the value of these services over the life of patients would be less than $400. Deferring benefit reductions was completely unwarranted.

The MoU required changes to CIED pricing to be finalised by June 2023. This did not occur, in part due to cardiac companies failing to provide information to MSAC as required by the MoU. The department has, therefore, only implemented partial pricing changes. To date, these delays have cost consumers more than $100 million in projected savings. Every additional week of delay is costing consumers more than $1 million.

Urgent action is required to protect consumers' and taxpayers' interests. Anything less than reducing the prices in line with the MoU would be unacceptable to health funds' members. The Australian Government should also consider clawing back some of the savings already foregone.

CIEDs are vastly overpriced on the PL. Prior to the pricing cuts, CIEDs were up to two and half times their price in the public system. The Department noted:

> "IHPA's analysis reveals that the public/private price gap for all cardiac devices is very large and price reductions for these devices will be key to achieving overall PL savings. For instance, for the most popular implanted defibrillator the PL benefit is around $36,500 and the public price is around $14,500." (FoI 4045)

The excessively high prices being charged for CIEDs must be addressed as a matter of urgency. During a cost-of-living crisis, consumers cannot afford to be financing the supernormal profits of multinational MedTech companies.

While the MoU provides a simple formula for reducing the prices of the devices, cardiac companies have argued there is a substantial cost to providing technical support services. The former Health Minister acquiesced and delayed the price cuts for CIEDs to allow MSAC to determine the true costs of providing technical support services.

The MoU notes:

> "MTAA will take all reasonable steps to ensure that cardiac companies that produce CIEDs commit to engage with MSAC (expected no later than March 2022) and provide MSAC during its deliberations described in section 2.4.1 with company data relevant to the MSAC process."

MSAC has determined that the reasonable cost to consumers of the technical support services is $44.4 million (based on 2021 data). However, Table 2 in MSAC 1724 highlights that the sponsors failed to provide the relevant data for MSAC to properly determine the costs per device. In a further attempt to delay price cuts, sponsors neglected to provide advice on how these funds should be distributed. Therefore, it is now up to the government to determine a fair approach that ensures consumers pay no more than the recommended $44.4 million for the technical support services.

PHA recognises the importance of technical support services for CIEDs, although we note that not all patients receive these services. The extraordinary high prices for CIEDs paid by private

patients includes technical support services, yet patients are currently required to pay twice with cardiac monitors *and* monitoring services also appearing on Part C of the PL.

MSAC has determined that the technical support services are worth $44.4 million per annum (based on 2021 volumes). Consumers are currently paying more than double this amount.

Prices should be reduced immediately. The MoU makes no provision for a phased reduction. Given the supernormal profits that CIED sponsors have enjoyed for many years at the expense of Australian consumers, there is no justification for further delays.

The proposed pricing changes for CIEDs were due to deliver around one third of the savings for consumers, due to the very high prices paid to international MedTech companies. Unfortunately, the delays in pricing cuts have meant medical device funding reforms have not delivered as expected for consumers. During a cost of living crisis, and increased pressure on many parts of the private health system, it is important that the government takes immediate steps to reduce the prices of CIEDs for consumers and taxpayers. A platform for ongoing reform is equally as important to ensure technical support services are delivered and this occurs under the supervision of treating medical practitioners.

4. Has prosthesis availability, clinician choice and patient access in Australia been maintained since the introduction of PL reforms?

Medical device choice has been maintained, regardless of quality, efficacy, effectiveness or safety.

5. In your view, to what extent have the PL reforms impacted on private health insurance premiums and coverage?

Since the commencement of the MoU, the average cost of medical devices per insured person has increased from $190 to $197. Although health insurance premiums increased on average by 3.03% in 2024, medical device spend increased by 3.7%. Medical devices represent under 9% of total PHI spend, as such, a factional price decline offset with a growth in volume means the reforms have had no impact on the overall viability of premiums and coverage.

Device prices, however, are very important to the overall viability of a competitive PHI market. Current reforms remain slow and delayed by the interests of those who benefit from the status quo. Further PL reforms could help ease pressure on health insurance premiums in future and reduce the risk of people reducing their coverage.

6. What are your views on the reform project to regroup the PL (with the aim of grouping devices by similar intended use per health outcome)?

Grouping devices by similar intended use per health outcome would increase scrutiny of Health Technology Assessments (HTA) over the PL and remove known flaws. Descriptions and grouping could have been more tightly aligned and sponsors held to account.

Groupings could also provide better clarity around clinical conditions or procedures specific prostheses are intended to be used, and in cases where devices are being used for procedures other than its intended use, whether it is priced appropriately.

PHA was comfortable with the Hereco report on regrouping the PL according to clinical function rather than device characteristics. It is profoundly disappointing that the department has abandoned this work (for now) following pressure from the device companies.

Following this decision, consumers are continuing to pay premiums for devices that have no additional clinical benefits.

7. What are your views on general use items (GUIs) staying on the PL?

PHA does not support the continued inclusion of GUIs on the PL. The 2020 Ernst and Young report, commissioned by the department, showcased multiple levels of abuse and likely fraud associated with GUI remaining on the PL. It was also critical of the lack of quantity controls or requirement to have devices that are PL funded linked to the actual surgery where the devices would be considered critical or even appropriate. Yet against these recommendations, which were supported by work by the Independent Health and Aged Care Pricing Authority (IHACPA), Grattan Institute and PHA among others, to move to a case-based payment or Diagnosis-Related Group (DRG) model consistent with the public system and what applies globally, the department opted to instead bow to pressure being applied by the device sector and the private hospital sector.

Further, the department continues to maintain significant errors in Part D of the list, and has not progressed consumer protection measures suggested by PHA.

8. What are your views on the updated PL assessment pathways?

The assessment pathways are not transparent to health funds. While we accept the decision made to remove the health insurance, device and private hospital representatives on MDHTAC, our member funds still have a right to understand potential substantive cost drivers prior to listings on the PL, and the reasons for decisions. Over time, many devices and procedures such the drug eluting stents, TAVI and AF listing have resulted in massive changes in annual PL spend, with very little transparency to expected volumes or outcomes.

Although the pathways approach is seeking to deliver on the HTA principles, decisions continue to be overridden by poor decisions made above the department's remit. This includes the MoU signed by a previous Health Minister that blocked the HTA-informed new grouping structure, and the decision to keep general use items on the PL.

9. What are your views on updated PL governance arrangements?

PHA supports the decision to remove representatives of private hospitals, the MTAA and health insurers from MDHTAC due to the conflicting commercial interests. But more accountability from the department, MDHTAC and CAGs is necessary to address errors found prior to PL listing cycles. Action also needs to be urgently taken when items are listed in error or made in good faith but are shown to be abusing the principles of HTA or the rules covering listing.

10. What are your views on the process and outcomes of the post-listing review framework published by the Department, and its guidance of the four pilot post-listing reviews?

In principle, post listing reviews are a sound approach to assessing HTA value being delivered by a device class. This was flagged as far back as 2019, but in 2025, a number of the recommendations are either still to be implemented or were started for implementation then reversed.

The department's priority should be to return value to Australian consumers and taxpayers given the government's contribution to health insurance through the PHI rebate. When reviews elect to remove substantial cost for a PL grouping (i.e. removal or re-setting of the benchmark), this becomes better than cost neutral for the investment made. As such, a closer look into this critical area of HTA reform is not only justified but would be cost positive to taxpayers.

PHA supports this process for the period in which a flawed PL mechanism remains. In a proper cost effective HTA-involved structure, as seen in the public system and globally, the decision to fund devices or groups of devices and their benefit is determined exclusively on the value those items provide back to the health system.

Health funds are happy to pay for devices that improve members' lives and are cost effective against alternatives supplied in the market that are provided at higher cost and with lower efficacy. But the current method of payment instead rewards device companies and hospitals that engage in rebates to use more expensive devices with or without evidence of value, and more items than required when compared to other, more efficient health systems.

A closer look at spinal cord stimulators, for example, has found evidence of their ineffectiveness across a number of recipients and deliberate gaming of the PL to force permanent leads to be funded by PHI in trials, when trial leads are provided globally for these systems from the same companies. This deliberate gaming has been shown to add millions of dollars in pure waste alone.

Post listing reviews are good, but they need to be actioned. Current efforts to either derail or delay them suggest commercial benefit for hospitals and sponsors is, unfortunately, prioritised over the health of privately insured Australians.

As mentioned above, the example of the department failing to implement the review of surgical guides and biomodels is particularly disappointing. The massive increase in costs to consumers for surgical guides and biomodels on the PL is a policy failure by the government that has enabled an entire industry of low value care to emerge. It has cost consumers and taxpayers tens of millions of dollars.

PHA first warned the department of the emerging issues with surgical guides and biomodels in 2019. More than five years later, our conservative estimate is that in excess of $80 million has been wasted.

The first review recommended limiting the use of surgical guides and biomodels to complex CMF surgery; the department did not implement the review recommendation.

A poor regulatory approach has fostered low-value care, rampant abuse and opened the industry up to potential corruption with some sponsors offering payments to providers, making threats to patients, and gouging consumers with outrageously high costs.

All of these problems are for a technology that is, at best, marginally useful in most instances, albeit very important in a few instances. It is also a low-cost technology with minimal marginal costs of production, which has been paid on a per-unit approach wholly unsuited to the costs and benefits of the technology. In other areas of the PL, these devices have been deemed as not eligible for listing, yet are widely used as they are cheap and easy to produce.

The Hereco report states:

> "No convincing data were identified to support the use of patient-matched surgical guides and/or biomodels is more effective or safer than conventional procedures without the use of such devices."

Based on this conclusion, there is no justification for biomodels and surgical guides to be listed on the PL.

PHA acknowledges that some surgeons use surgical guides for very complex CMF procedures, and health funds are willing to continue supporting reimbursement for surgical guides in these complex procedures where there is evidence of efficiency, despite the lack of evidence of effectiveness. This approach is consistent with the first report.

In the six years since PHA highlighted the problems with surgical guides and biomodels, the department has not properly addressed the issues, nor taken the independent advice they commissioned to remove benefits from low-complexity procedures.

11. What are your views on the compliance strategy and processes the Department has implemented during the PL reforms?

The compliance strategies and processes implemented by the Department during the PL reforms remain inadequate. The lack of transparency and accountability in certain areas enables device companies to roll the dice on gaming the system, hence fraud and abuse continues. Little is being done to improve compliance.

The current opacity of which items consumers and taxpayers are paying for cannot be justified. Clear evidence of what product codes are being claimed under a billing code should be publicly available. All sponsors and private hospitals already have the product codes linked to billing codes within their internal systems as this is necessary for individual items to be invoiced correctly. Making it available to everyone would enable health funds, hospitals and competing device companies use it to find and address abuses.

There should be no justification for device suppliers, the MTAA or hospitals objecting to product codes being displayed so invoices can be checked to ensure codes are able to be claimed under the PL code. This would ensure transparency.

The department must hold an accurate register of every supplier product code listed in a billing code and this must be able to be scrutinised by all stakeholders in the system.

PHA has regularly highlighted PL errors, yet the department has failed to consider this evidence in a reasonable timeframe. As at 29 May 2025, the following issues have been identified and not yet addressed:

- 19 May 2023 - PEEK material in SF096 and SF151 "absorbable" screws
- 25 August 2023 - Category review for MN322 poly liner
- 17 November 2023 - splints on the PL
- 20 November 2023 - incorrect ARTGs
- 16 February 2024 - double billing FL012
- 26 March 2024 - Dura patches being used in bariatric surgery
- 27 March 2024 - condition on ST884 pins when used as surgical tools
- 28 March 2024 - remote monitoring conditions
- 2 July 2024, 20 August 2024, 22 November 2024 - spinal cages (noting some issues are currently being addressed)
- 20 August 2024 - knee errors on PL
- 21 August 2024 - specialist ortho errors on PL (noting some issues are currently being addressed)
- 28 November 2024 - review of 13.02.01 – Nut/Set Screw/Locking Screws
- 29 November 2024 - MDHTAC items not actioned
- 5 December 2024 - meeting request re misleading stakeholder feedback reports (meeting has occurred)
- 11 December 2024 - TYRX envelope
- 7 January 2025 – DU065 spinal disc system being billed for separate components (dept acknowledged, looking at this with other similar items)
- 13 January 2025 – pedicle screws in wrong sub-group
- 22 January 2025 – Stryker knee hinge system being billed for separate components
- 12 March 2025 – Stryker billing twice for ankle components, despite department instructions not to do so in 2018
- 14 March 2025 – Australian Allograft multiple billing
- 14 March 2025 – Australian Allograft billing for very large volumes of human tissue products
- 17 March 2025 - Australian Allograft alleged commercial arrangements trading in human tissue
- 24 March 2025 – spinal cord stimulators recommended price reductions not implemented
- 31 March 2025 – Stryker billing twice for elbow components

While PHA is very pleased as the work the department has done to bring more rigour into new listing on the PL, the pre-2019 system encouraged some dreadful consumer outcomes. The department has been too slow to clean up the problems with items already on the list.

12. What are your views on the ongoing financial sustainability of the Department's administration of the PL?

PHA does not support the continuation of the PL. While it may have had merit in 1985 with a small base of products, supplier codes and sponsors, it is now a totally inadequate way to manage a $2.4 billion annual spend. The Australian private health market needs to adopt the standard mechanisms relied upon globally, which will also remove the inefficiencies and visible or identified waste that the PL enables.

As much as 60% of the PL is overpriced (like stents/pacemakers) against routine competitive forces. The same companies that protest a competitive non-PL procurement model are the same companies that compete globally in these more efficient markets. These are globally manufactured devices using sophisticated global transfer pricing and other means to strip excess profits from Australia. This is a direct transfer of wealth from the 15 million Australians who hold PHI as well as those that support PHI in some form through taxation via the PL Rebate.

Device suppliers and private hospitals are routinely advocating for less government intervention, regulation and cost, yet when it comes to retaining the 40-year-old outdated model that is the PL, and the department infrastructure needed to sustain it, they advocate for it to be kept (without any compliance or accountability measures or HTA considerations prior to items receiving a protected price, that is).

PHA will continue advocating for a move to a DRG or bundled payment model. This would free up precious department resources to assess new technologies and HTA. It would also reduce the cost of prostheses by around 25%, which would ultimately lead to a reduction in the cost of health insurance for Australian consumers.