Private Healthcare Australia
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Prostheses List Reforms – Paper 7

Proposed measures for compliance, assurance and information sharing

August 2023

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 24 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 over 14 million Australians.

Response

PHA welcomes the establishment of a Prostheses List compliance strategy team within the Department of Health and Aged Care (DoHAC) as it provides an opportunity to improve the integrity of the scheme and benefit consumers. PHA broadly supports the proposed measures for compliance, assurance and information sharing.

Our submission will address the general principles, then make specific comments on the proposed measures.

In general, PHA supports:

- Shared responsibility for responsible use of and access to medical devices.
- A greater focus by the department to monitor compliance.
- The policy principles used for developing the proposed measures.
- Introducing 'conditions of listing' to prevent low value care.
- The new rules for specifying record keeping and notification requirements.
- Legislative instruments available to address non-compliance.
- The proposed information sharing between government agencies, and
- The proposal for sponsors of listed devices or products to be disqualified from being a sponsor for a listed device or product if convicted of a criminal offence.

We ask DoHAC to consider the following additional improper practices to address the objectives of the compliance strategy.

- Addressing low value care, and
- Sales representatives in surgery without the explicit permission of the patient.

General points

Do you support the concept of a 'shared responsibility' for safeguarding the Prescribed List? If not, then why not?

PHA supports the concept of shared responsibility. However, the language of "safeguarding the Prescribed List" is borrowed from the device industry to safeguard a payment mechanism rather than to protect the consumer.

PHA recommends that the language be amended to a shared responsibility to ensure that Australian consumers have access to quality medical devices and human tissue products, used as intended, at a reasonable price.

DoHAC has previously suggested a range of payment mechanisms to achieve the policy outcomes, including a list system preferred by international medtech companies, and a diagnostic reference

group approach, favoured by PHA and other stakeholders. Safeguarding one payment option when others would provide greater community benefit is not necessary - safeguarding the policy outcomes is a better approach.

There is significant scope for sponsors, hospitals and DoHAC to do more to protect quality, safety, efficiency and value, and we look forward to sharing that responsibility.

Do you agree with the policy principles used for developing the proposed measures?

PHA supports the policy principles, and makes the following comments:

- Active management of listed devices and products will make a substantial difference to integrity; these measures are supported.
- Informed decision making is important, not just to the government and industry, but to hospitals, payors and consumers. Informed decision making requires greater transparency.

The listed principles are supported but would be assisted by adding a specific principle on transparency.

We also recommend that the compliance strategy outlines the need to move towards competitive neutrality between medical devices and pharmaceuticals. There is no reason that the compliance regimes should be different, and there is potential harm if the differences between the regimes result in preferences for one type of treatment over another. There is significant evidence that some devices are overused in Australia.

The need for comprehensive information to drive transparency and scrutiny

Greater transparency will prevent the need for more punitive measures being deployed. For example, transparency of product codes that sit within billing codes, and links to appropriate MBS items will remove a substantial amount of abuse and low value care.

The department should continue to improve the accuracy of content on the PL which currently includes multiple sub-groups, incorrect and invalid ARTG numbers, suffix, and vague definitions of devices due to a previous lack of oversight. This should be matched with a greater degree of transparency.

Sponsors should be publicly providing:

- Accurate code information including a full list of manufacturer product codes covered under each PL billing code.
- Accurate cost information.
- Information such as the Indications for use (IFU) and contraindications for devices.

Sponsors and DoHAC also have an obligation to reduce and prevent low value care by ensuring the use of medical devices is evidence-based. PHA supports a stronger mechanism to link prescribed items to procedures where they are shown to have a positive HTA. The current framework, with few exceptions does not limit access to MBS/ICD-10 codes where the device is proven to be cost effective. Addressing this will help prevent excessive use of items and unnecessary treatments.

A clear understanding of which devices (and their product codes and system brands) sit within a billing code is critical to accountability and confidence in the authenticity of listings, as well as DoHAC's ability to do comparative post listing reviews with the public system and international markets.

Medical devices should only be funded in surgical procedures where the CAG, PLAC and potentially MSAC have reviewed this to be clinically and cost effective, or where the treating medical practitioner confirms that the use of the item in other circumstances is reasonable and necessary.

By assigning devices to only known MBS conditions that are cost effective, all stakeholders can have greater confidence that sales representatives are not upselling PL listed items into low value indications. This will improve efficiency, efficacy and is likely to reduce patient risk.

The pharmaceutical regulatory regime provides a guide. There is no reason for medical devices to have a lighter compliance regime than pharmaceuticals.

Should additional compliance measures be considered?

Low value care and health care variation

There is significant variation in the use of medical devices, and several clear examples of low value care. Safeguarding consumer interests should include reducing and eliminating low value care.

The PHI sector is susceptible to miscoding and low value care. There is a culture in the private sector among some providers that views private health funds as 'passive payors' whose funding is an entitlement for providers and not fund members.

Private health insurance funding is also highly contested compared with other funding models in health, with powerful vested interest groups such as multinational device companies, and hospital groups all vying for their share of the pie. In an inflationary environment it is critical that every dollar spent in this sector is productive and adds measurable value. Too often historical funding models under the health portfolio compel expenditure in ways that are wasteful and even harmful.

There are several studies available highlighting low value care. The work of Choosing Wisely and the Australian Council for Quality and Safety in Healthcare (ACQSHC) highlights areas of low value care, and Australia has a strong academic and professional capacity to identify and anticipate loopholes in the PL vulnerable to exploitation.

Reducing low value care is important across the health sector. The PL should drive best value care, not facilitate low value or harmful care.

All parties – governments, funders, suppliers and hospitals - have an obligation to reduce and prevent low value care by ensuring devices are used in an evidence-based manner. To this end, PHA supports a stronger mechanism to link prescribed items to procedures where they are shown to have a positive HTA. The current framework (with few exceptions) does not restrict access to devices to MBS/ICD-10 codes where the device is proven to be cost effective. The Australian Government restricts the use of pharmaceuticals to specific indications, and there is no reason that medical devices should be treated differently. Adding conditions to listing will help prevent low value care and reduce the potential for harm.

Medical device representatives in surgery

Currently, no Australian jurisdiction provides legislative guidance to ensure surgical patients are aware of non-clinical staff who are not hospital employees, being present in operating theatres.

Legislative changes to the Act provide an opportunity to ensure that patients are required to give consent for observers, sales representatives, and private sector technicians to be present in the operating theatre during surgery.

This legislation is necessary as it is common practice in the private sector for medical device sales representatives to be present in theatre to provide technical advice to clinical staff and/or promote their products. Patient groups are largely unaware that sales representatives are permitted in operating theatres, although clinical advisers confirm it is common practice.

Furthermore, there is an inherent conflict of interest. A sales representative whose primary purpose is to undertake commercial activities, and who reports to the commercial division of their parent company may not necessarily act in the best interests of the patient.

PHA recommends that the legislation be amended to ensure that patients are given the opportunity to consent to medical device sales representatives being present in theatre.

The proposed measures

Record keeping (1-3)

The record keeping proposed measures are reasonable, and in most cases would align with current requirements for medical records and auditing.

For the proposed measures for sponsors, PHA supports the objectives of these obligations to ensure that current and accurate information is available to demonstrate that listed devices and products remain safe, clinically effective and that the specified benefit for the device or product is proportionate to its clinical effectiveness. However, it is also important that the devices listed can be easily identified – currently it is not possible to accurately identify all items covered by the PL. As previously recommended, sponsors should be required to publicly provide:

- Accurate code information including a full list of manufacturer product codes covered under each PL billing code.
- Accurate cost information.
- Information such as the Indications for use (IFU) and contraindications for devices.

These data can be disclosed by sponsors, by government or ideally, both.

For the proposed measures for hospitals, nearly all of the information required about devices and products will be kept with the patients' medical record. PHA recommends that the relevant information about devices and products simply refer to the existing requirements for medical records.

The consultation paper mischaracterises rebates on PL items as normal commercial practice. A rebate paid from a supplier to a large client may be accepted normal practice but this is between the supplier and the payer. Hospital groups are not the end payers for the PL; health funds are the end payers on behalf of their customers. A rebate paid by suppliers to hospitals is simply taking a cut from an amount paid by funds on behalf of consumers. Transparency of these arrangements is vital to protect consumers' interests.

PHA supports additional transparency with a register for gifts and benefits. However, it is unclear why hospitals would be asked to keep an incomplete register of gifts and benefits limited to a particular type of free product. A kickback is a kickback, be it goods (of whatever type), cash or services.

If there is a requirement to disclose one type of 'kickback' and not others, then inducements will be provided in a manner not disclosed.

The Medicines Australia Code of Conduct is the benchmark. The Code includes "Transparency of payments and transfers of value", not limited to one type of 'kickback'. The transparency regime for medical devices should be consistent with the medicines code.

Offences and sanctions (4-8)

The current focus on education and cultural change needs to be supported with significant penalties. Regulatory theory demonstrates that the existence of penalties in and of itself promotes compliance.

We recommend the department consider the commercial impacts of non-compliance activities and penalties. The response to compliance breaches should be commensurate with the harm to consumers.

None of the errors PHA and DoHAC have identified over the last five years have seen the sponsor lose revenue, while the commercial impact to consumers has routinely been significant, totaling millions of dollars.

We agree that prevention is better than remediation via punitive measures.

PHA hopes and expects penalties are never applied. However, good governance suggests that penalties are at least equivalent to the revenues extracted from payers by any inappropriate activity. It is important that a culture does not develop where fines are simply seen as part of the cost of doing business. The Australian Competition Law allows for larger penalties where the consumer harm has been greater, or where the corporate entity is very large. PHA notes Heath Minister Mark Butler's interest in a proportional approach, recently stating: "I've asked in particular to see whether the penalties that are put in place for the most egregious examples of misconduct are proportionate."[2]

As the largest suppliers of medical devices are companies with turnover greater than some Australian states, small financial penalties may not be a sufficient deterrent.

For hospitals, it is difficult to envisage how a hospital would be able to commit an offence warranting revocation of declaration. Offences would be most unusual, and in nearly all cases, be related to falsifying medical records (where offences already exist). A new offence for hospitals providing false or misleading information about a listed device or product is not warranted.

A specific offence for making false declarations on gifts and benefits may be warranted, and any such offence should attract a fine rather than revocation.

Information sharing (9-10)

Do you think there are other agencies that should be authorised for disclosure of protected information? For example, professional associations for health care providers?

PHA recommends the Department be authorised to disclose information to the Australian Taxation Office (ATO) to help the ATO crack down on tax compliance issues, such as transfer pricing.

How might Public Summary Documents be introduced in an incremental manner? For example, what kinds of devices or products should first be required to have a Public Summary Document?

The Public Summary Document (PSD) should contain:

- a clear description of the device, and what is included (for example, accessories, systems)
- all manufacturer codes listed under the billing code
- the ARTG reference
- links to information such as the IFU and contraindications for devices, and
- for new devices added to the PL, the MBS item(s) the device was assessed against.

All items on the PL should have a PSD available from 1 July 2024, noting that existing devices will not be required to nominate the MBS items they were assessed against. The information is readily available to sponsors and there should be little additional cost in publicising this information.

Objectives of the Act (11)

Do you think the objects of the Act should be amended to recognise the expanded scope contemplated in the proposed measures? What do you think of the proposed additional object for the PHI Act?

The proposed additional objective appears redundant and is not supported.

The proposed wording also suggests that the medical technology industry is more important to the government than doctors and hospitals, followed by patients and heath fund members. PHA does not support this ordering.

Implementation

PHA notes that the proposed basic integrity measures have been absent from the legislation to date. Delays in implementation continue the existing risks to integrity and should be avoided where possible.

Review

The department is considering whether a statutory review should be provided for in the PHI Act so that there is an independent review of the measures introduced as part of the reforms. Would you support such a review and what would be important elements of the review from your perspective?

PHA supports a statutory review which is truly independent, objective and not subject to lobbying or capture by those who stand to benefit financially from maintaining the status quo.

The review should be conducted at arms-length by the ACCC under Part VIIA of the Competition and Consumer Act 2010. This will allow the Government to make an informed assessment of the program and how it operates, based on evidence, data and facts alone. Further, conducting an inquiry under Part VIIA will empower the ACCC to exercise its extensive statutory powers to obtain information or documents, and to compel potentially reluctant witnesses to answer questions on oath.

This inquiry should examine the following issues caused by the over-pricing of generic medical technology:

1. The impact on consumers of adding to the cost of surgery flowing through to premiums.
2. Pricing of generic medical devices compared with those same devices in other countries.
3. The distortion of markets caused by poor controls on the activities of sales representatives and the undisclosed rebates, secret commissions and other benefits paid to doctors and hospitals.

4. Additional costs of unnecessary devices that are being 'push-sold' by medical technology sales representatives being present in operating theatres, resulting in inflated overall costs to consumers of surgical procedures.
5. Enabling multinationals to pay minimal tax in Australia through transfer pricing against Protheses List benefits.
6. The anti-competitive effect on Australian manufacturing of generic medical technology as the multinationals have secured lucrative supply chains (through payment of benefits to doctors and hospitals) such that local businesses can no longer compete.
7. The inflationary impact on public hospital procurement and costs of the floor price set by the Federal Government, and
8. The economic and health risks created by inflated benefits, and the effects this has on the quality of care – noting, for example, the lives of Australians impacted by the upselling of pelvic mesh for an inappropriate indication and other examples.

A truly independent review by the ACCC, which sits outside the usual health sector interests and lobbyists, will be able to provide the Government with reliable data and economic analysis as to why the present Prescribed List must change. This will enable health funds to direct savings — running into billions of dollars — back to consumers or to high-value healthcare.