Private Healthcare Australia
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Response to the Prostheses List compliance strategy framework

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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 to the framework

Private Healthcare Australia (PHA) welcomes the establishment of a Prostheses List compliance strategy team within the Department of Health. This body of work has a real opportunity to improve the integrity of the scheme and provide significant consumer benefit.

In sum, PHA supports the draft strategy. For brevity we will only add additional comment to the points where risk exposure needs detailed focus.

PHA supports:

- The purpose of the strategy in the context of the department's plans
- The three principles of regulatory best practice
- The four points compliance priorities
- Greater focus by the department in monitoring compliance
- The compliance approach, with tiers of non-compliance
- Mechanisms for identifying non-compliance including data and tip-offs
- The use of referrals to and from other agencies
- Legislative instruments available to address non-compliance
- Principles the department will take in delivering compliance activities including values, procedural fairness (including to consumers and payors) and privacy

The areas that are most critical to success in delivering the compliance strategy are listed below.

Reducing the potential for compliance breaches through improved PL listing controls. This should be achieved through the substantial tightening of the listing process, including conditions on listing where the benefit is automatically payable only for the MBS items (or ICD codes) for which it has been assessed, or where a medical practitioner certifies that the use of the product is reasonable and necessary.[1]

This approach should also address marketing and promotion of devices for areas outside those approved for use and/or not assessed for efficacy or efficiency.

Regrouping the PL will ensure that there will be fewer areas of dispute and more opportunity to reduce low value care, as the benefits payable by consumers will be more consistent with clinical function rather than device characteristics.

[1] PHA have provided previous information to the Department on conditional listing.

Staged penalties. The initial 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. PHA recommends that the penalties for non-compliance be part of the first set of proposed legislation, although we support staged introduction of compliance functions.

We recommend that 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. The Australian Competition Law allows for larger penalties where the consumer harm has been greater, or where the corporate entity is very large. 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.

None of the errors PHA and the department have called out over the last five years have seen the sponsor lose revenue, while the commercial impact to payers has routinely been in the range of $100,000 - $3.5 million per issue. The penalties for lack of compliance should not be significant excess profits for multinational companies.

PHA notes Minister Butler's interest in this 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]

Urgency of response. Errors need to be corrected much more quickly. Delays of weeks or months are currently costing consumers millions of dollars. For example, it took more than a year for the department to act on a bolt used in external fixation to be repriced from $1023 to $45. This delay cost consumers over $600,000, and despite requests to the sponsor, has never been repaid to consumers. The delay in removing Stratafix (an ineligible suture) cost consumers over $2.5 million.

A no regrets approach to patient safety. Where patient safety is the issue, the department must move much more quickly – in this case the natural justice for consumers should trump natural justice for device companies. The delays in removing pelvic mesh from the market provides the clearest example where a lack of action resulted in consumer harm. The delay in requiring the benefits for INFUSE bone graft substitute to be matched to the ARTG conditions may have resulted in patient harm (and in this instance, the sponsor withdrew the product rather than the department ensure that the use of the item on the PL was suitable).

PHA welcomes the strong commitment the department has shown to addressing non-compliant activity relating to the Prostheses List. Many of the steps already taken, such as linking billing codes to HTA cost effective MBS and a clear list of manufacturers product codes listed under each billing code (soon to be publicly available) reduce non-compliance and wasteful spending.

Improved transparency and a solid compliance program should reduce wasteful spending and improve public value.

[2] The Hon Mark Butler MP, Minister for Health and Aged Care, 730 transcript, 18 October 2022

The consumer protections for the use of medical devices should move towards regulatory consistency with other areas, in particular pharmaceuticals. PHA notes that there are other steps that needs to be addressed that sit outside this framework (such as an ACCC-endorsed code of conduct, aligned Health Technology Assessment approaches and reasonable pricing frameworks) to ensure consistent approaches to maximise consumer value and protection. This framework is an important step towards consistency and should improve public value.