PROSTHESES LIST COMPLIANCE STRATEGY SUBMISSION RESPONSES ANALYSIS

Introduction

The purpose of this report is to provide an analysis of stakeholder feedback received in response to the proposed Prostheses List Compliance Strategy (the Strategy). The submission period for responses to this Strategy occurred between 14 September and 21 October 2022. A total of 21 submissions were received and accepted by the submission deadline (Figure 1). The submissions represented the medical technology sector, private hospitals, private health insurers, clinical experts and individual consultants.

Evaluation of the submissions considered feedback about the proposed Strategy, specifically regarding the Prostheses List (PL) compliance obligations, compliance activities, types of practices and behaviours that constitute non-compliance, and the legislative instruments applicable to the PL program.
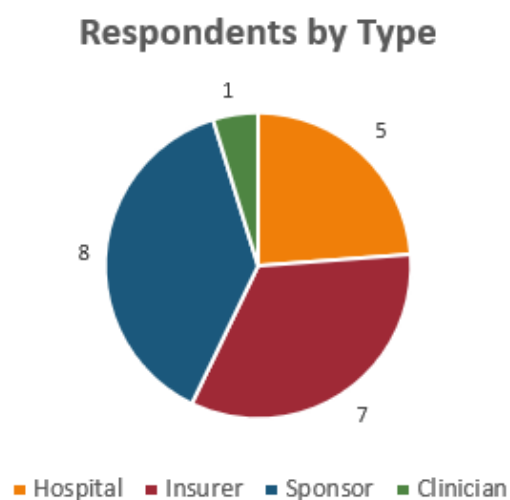

Respondents by Type

- Hospital
- Insurer
- Sponsor
- Clinician

Figure 1: Number and type of respondents to Prostheses List Compliance Strategy.

Key feedback

Most PL stakeholders acknowledged and supported the proposed Strategy. Key recommendations were about the need for:

- Clarification of expectations or obligations for PL stakeholders including hospitals and insurers

- Clarification of PL compliance enforcement activities with possible case studies

- Inclusion of additional types of non-compliant practices that need to be addressed.

While stakeholders indicated a general understanding of the legislative instruments, there were requests for additional education and training specifically aimed at those who administer and interact directly with the PL.

Key concerns

Some of the concerns raised by stakeholders about the Strategy include:

- Enforcement measures must be not only timely, but consistent and sufficiently robust to act as a deterrent of deliberate non-compliant activity
- With the establishment of a formal compliance model, there needs to be an appropriate way to appeal decisions and actions taken by the Department.

An overview of stakeholder's feedback on the Strategy, as well as the Department's response to the feedback is summarised in Table 1.

Outside the scope

Several issues were raised by stakeholders that were outside the scope of the Strategy and these were therefore not included in the analysis. These included insights on the broader PL program rather than compliance related matters, such as monitoring comparative international markets, reference pricing and the revised cost-recovery model.

These issues will be considered separately as part of the PL Reform.

Table 1: Key feedback and concerns about the proposed Prostheses List Compliance Strategy raised by stakeholders and the Department's accompanying response to address stakeholder concern.

Issue	Stakeholder feedback	Department response
Clarity about the responsibilities of stakeholders	Many stakeholders raised concerns about the lack of clear understanding of responsibilities/measures applicable to each PL stakeholder group.	The Department acknowledges the feedback provided by stakeholders. The list of obligations and simple measures is not intended to be exhaustive but would benefit from clarifying those that are applicable to the different stakeholder groups. Additional descriptions have been added to the Strategy.
Clarity about compliance enforcement activities	Some stakeholders raised their concerns regarding a lack of clarity around the exact nature of compliance enforcement activities in the PL Compliance Enforcement Model. Feedback indicated a need for more details about the strategies and the method of implementation.	The Department notes that more information has been requested by respondents regarding the PL compliance enforcement model and the method of implementation. The Department plans to use hypothetical scenarios as case studies to help communicate and build understanding of the new activities.
Timings	Some stakeholders expressed the urgency for errors to be corrected more promptly on the basis that delays cause unnecessary financial burden for consumers.	A key principle that underpins the PL approach to compliance is that decisions are risk and evidence based. The Department will act responsively where there is a risk to patient safety. Additionally, resources and effort will be prioritised according to the likelihood and consequence of the compliance concerns. Errors that are administrative in nature (i.e. not a matter of non-compliance) will be addressed as soon as is practicable i.e. next PL update following the identification of the matter.

Issue	Stakeholder feedback	Department response
Improve PL listing controls	Feedback suggested introduction of additional listing controls, such as linking billing codes to specific Medicare Benefits Schedule (MBS) and International Classification of Diseases (ICD) codes to ensure usage is clinically appropriate. This also includes conditions on listing where the benefit is automatically payable only for the MBS items (or ICD codes).	These measures are currently available as risk-based controls and will continue to be used where appropriate.
Utilisation	Stakeholders raised concerns about the need for prostheses utilisation to consider changes in clinical practice, funding and contractual arrangements between insurers and hospitals. The Department's "significant increases" terminology needs to have a quantifiable metric or threshold to trigger a review.	The Department will consider including these factors in the utilisation analysis undertaken when assessing suspected non-compliance i.e. in Post-listing reviews and other monitoring activities.
Identifying and reporting non-compliance	Feedback suggests a formal framework be implemented for the identification and reporting of non-compliance. Stakeholders recommended a 'reporting portal' be included in either the Department's webpage or as a function within the HPP.	The Department has established a 'tip line' mechanism using a dedicated 'inbox' for the reporting of suspected non-compliant activities/behaviours.
Transparency	The process needs to adopt, including legislatively, all elements of procedural fairness such as consultation, reviews and appeals.	The Department has obligations to ensure the PL program is performing effectively in meeting the policy objectives. The Department is expected to ensure actions are risk-based and proportionate and that actions are timely to minimise harmful impacts, maximise deterrence and provide certainty. Consultation with relevant stakeholders will continue to feature as a key activity to provide opportunities for input and feedback.

Issue	Stakeholder feedback	Department response
Removal of billing codes	Stakeholders emphasised that the removal of dormant or sleeper billing codes, is a critical compliance step. The mere retention of old codes with a low annual re-listing fee, and no valid ARTG, are being used as a "comparator" often for vastly different technology.	The Department will address matters of suspected non-compliance on a case by case basis. Where stakeholders have specific concerns, they are encouraged to contact the Department and provide all relevant information to support further consideration.
Guidance and education	Stakeholders requested to have comprehensive education and training for all those who administer and interact with the PL. It would be beneficial to clearly lay out how legislative instruments are applicable in terms of compliance obligations.	The Department will provide stakeholders with education and guidance notices to understand the new compliance functions and activities. We will also provide case studies about compliance related matters as an education tool aimed at encouraging voluntary compliance.
Additional types of non-compliant practices to be addressed	Stakeholders raised concerns about a number of different types of non-compliant practices that some insurers, hospitals, sponsors and clinicians were undertaking in their dealings with the PL.	The Department will assess each of these concerns and where the issue is within the scope of the PL, will look at ways these concerns can be addressed.
Non-compliance categories	Stakeholders stated that it was hard to differentiate between the 'Minimal non-compliance' and 'Minor non-compliance' tiers on the PL compliance enforcement model.	The Department acknowledges that there are very little differences between the minimal and minor non-compliance categories and will consolidate these into 'Minor non-compliance'.