Proposed measures for compliance, assurance and information sharing

Prostheses List Reform Taskforce

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Questions and feedback

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Questions will be answered after our presentation.

Questions not related to the topics discussed today will not be addressed.

Webinar materials

This webinar is being recorded.

A link to the recording and copy of the slides will be sent to attendees after the webinar.

Agenda

1. Introduction
2. Overview of the proposed measures for compliance and assurance
3. Overview of the proposed measures for information sharing
4. Overview of the proposed additional measure
5. Proposed implementation timeline
6. Stakeholder impact
7. Opportunity for stakeholders to ask questions or provide feedback on the proposed measures.

1. Introduction

Why are we proposing compliance, assurance and information sharing measures?

01

Measures are needed to safeguard the integrity of the PL, and for devices and products to remain safe, clinically effective and with a benefit that is proportionate to its clinical effectiveness

02

Currently, there are limited requirements from stakeholders after a device or product is listed in the PL.

03

Current ongoing maintenance of the PL relies on ad hoc reviews by the department, or information voluntarily provided by sponsors

04

Without records and information, monitoring the clinical or cost effectiveness of listed devices and products and their appropriate use after they are included in the PL becomes difficult.

How can we safeguard the Prescribed List?

This could be achieved through:

01

Active management of listed devices and products

Further encouraging sponsors to actively manage listed devices and products for which sponsors are responsible

02

Informed decision making

Continuing to provide for informed decision making about listed devices and products based on the most contemporary and accurate information

03

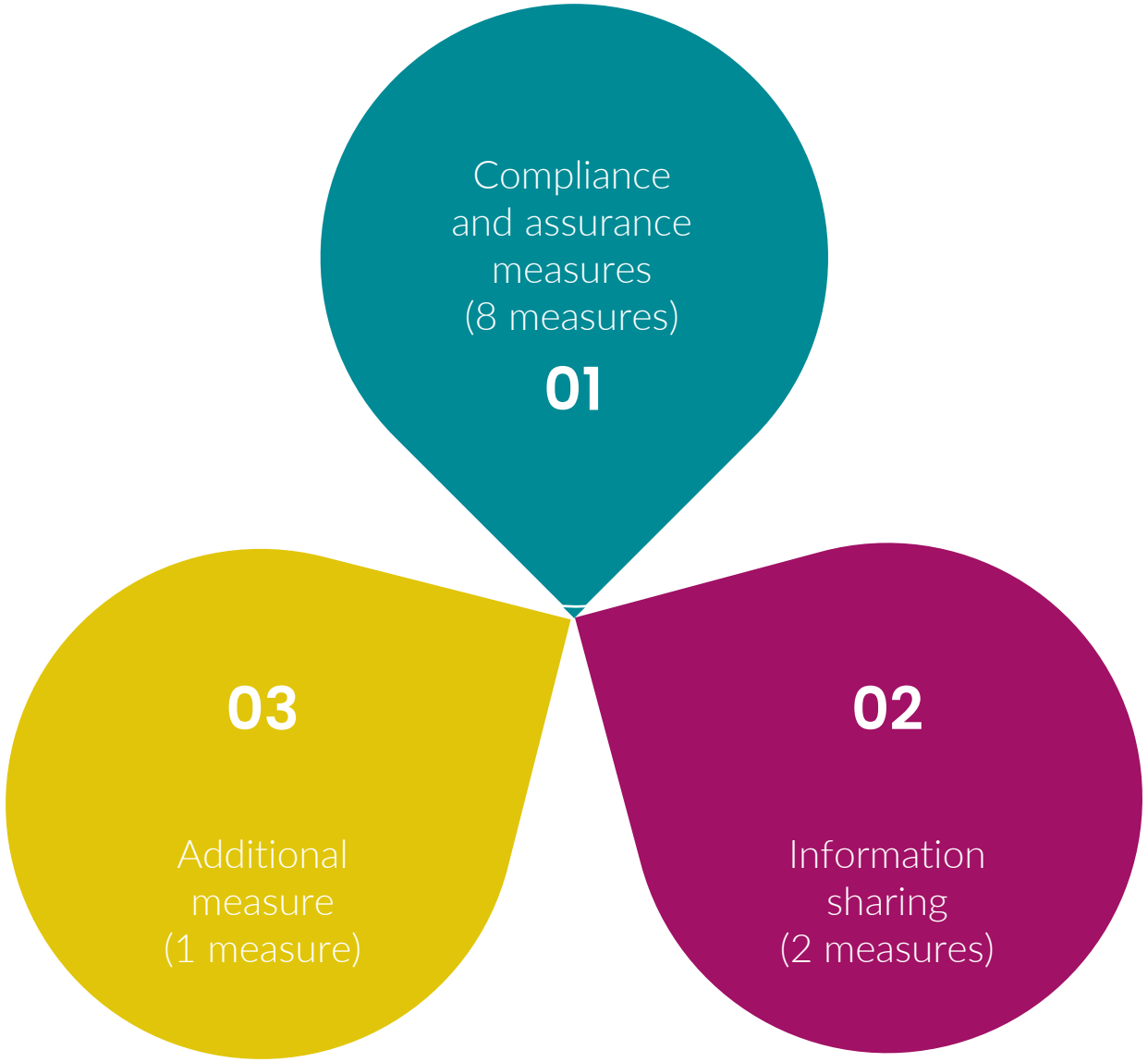
Responding

Ensuring the Minister can respond to, and inform other relevant agencies of, issues or concerns about listed devices or products

Principles used to develop the proposed measures

1. To implement preventative measures with the intention of 'assuring' compliance and reducing the need for punitive measures
2. To transparently specify the obligations for all relevant entities
3. To provide for proportionate responses to suspected non-compliance, based on accurate information that is readily available
4. To provide that entities are regulated consistently under the PHI Act, so that equivalent measures (including penalties) apply to insurers and healthcare providers (hospitals and sponsors), while recognising the 'tool' for imposing the measures may be different
5. To align with therapeutic goods legislation and existing measures in the PHI Act where this minimises regulatory burden and promotes compliance, so regulated entities can comply with proposed measures as part of other existing regulatory requirements
6. To constrain proposed measures to listed devices or products in the PL, or circumstances in connection with listed devices or products in the PL, to minimise impacts on other provisions in the PHI Act, including regulatory impacts

2. Overview of the proposed measures for compliance and assurance



01 For sponsors

Proposed measures	Purpose	Proposed implementation
The following record keeping and notification obligations: a. make and keep records about a listed device or product b. provide records about a listed device or product c. provide relevant information about a listed device or product d. provide correct information about a listed device or product (when incorrect information has previously been provided) e. ensure records made, kept or provided are in the approved form f. provide any other information-related obligations.	• ensure that information is current and accurate • listed devices and products remain safe and clinically effective • specified benefits are proportionate to clinical effectiveness • encourage sponsors to actively manage listed devices and products • promote public confidence in the Prescribed List.	• include new conditions of listing in the PHI Act or • specify obligations in the *MDHTP Rules* and require compliance through criminal offence

02 For hospitals

Proposed measure	Purpose	Proposed implementation
Same record keeping and notification obligations as for sponsors, but with any specifications included in the *Private Health Insurance (Health Insurance Business) Rules.* An additional obligation for hospitals is to maintain a register and report non-financial gifts and benefits: • only in relation to provision and/or procurement of devices or products on the PL • only if the gift or benefit was a device or product on the PL. There is no proposal to include any sanctions or penalties regarding non-financial gifts or benefits. However, there are proposed penalties for giving false or misleading information on this matter.	For record keeping and notification obligations: • same purpose as for sponsors • to provide transparency behind claims for PL benefits. For declaration of non-financial gifts and benefits obligations: • to reduce the number of claims for benefits for items on the PL when there is no associated cost for the device or product.	• specify these obligations in the *Private Health Insurance (Health Insurance Business) Rules* or • legislating these requirements in the PHI Act (to provide for more transparency). For example, these obligations could be implemented by amending the PHI Act to specifically provide that conditions on declarations for hospitals include the proposed obligations.

03 For insurers

Proposed measure	Purpose	Proposed implementation
Same record keeping and notification obligations as for sponsors and hospitals, only for records that would be relevant for insurers to keep and provide. Any specifications included in the *Private Health Insurance (Complying Product) Rules.*	For record keeping and notification obligations: • same purpose as for sponsors and hospitals	To specify these obligations in the *Private Health Insurance (Complying Product) Rules.* Legislating these requirements in the PHI Act would provide for more transparency.

04 Specific offences

It is proposed that:

- offences for refusing or failing to comply with the record keeping and notification obligations NOT be included in the PHI Act

- the PHI Act be amended to provide that the regulations may prescribe the following:

a. requirements for the making, keeping and providing of records about listed devices or products or in connection with listed devices or products

b. requirements for the provision of relevant information about listed devices or products

c. requirements for the provision of corrected information about listed devices or products

d. offences, not exceeding 20 penalty units, for refusing or failing to comply with a prescribed requirement in the regulations

04 Specific offences (continued)

- These regulations would only be made if administrative sanctions were found to be insufficient or inappropriate for achieving compliance with the record keeping and notification obligations.

- This policy would operate by repealing any record keeping or notification obligations from the relevant *Rules* and prescribing obligations and offences in the regulations.

- This measure may never be needed (and regulations may not be required) if substantial compliance with the proposed measures above is demonstrated.

- This measure could be implemented alongside the introduction of infringement notices in the PHI Act, so that there would be a graduated means of implementing the obligations and criminal offences for not complying with these obligations.

Administrative sanctions

	Sponsors	Hospitals
05 **For refusing or failing to comply with record keeping and notification obligations**	PHI Act be amended to provide for removal of a device or product from the PL. The exercise of this power would be subject to Administrative Appeals Tribunal review.	PHI Act be amended to provide that a declaration for a hospital may be revoked. Revoking a declaration of a hospital will continue to be subject to Administrative Appeals Tribunal review. This measure may be implemented more proportionately through providing for injunctions or enforceable undertakings rather than through revoking a declaration or removing a listed device or product.
06 **For false or misleading information about a device or product**	PHI Act be amended to provide for removal of a device or product from the PL. The exercise of this power would be subject to Administrative Appeals Tribunal review. This proposed measure addresses cross-subsidisation by providing for the removal of a listed device or product, without the need to conduct a new full evaluation.	PHI Act be amended to provide that a declaration for a hospital may be revoked. The exercise of this power would be subject to Administrative Appeals Tribunal review.

07 Criminal sanctions

It is proposed that the PHI Act be amended to include offences (aggravated, underlying and strict liability) for providing false or misleading information:

- in connection with a listed device or product
- in an application to list a device or product in the PL

1

Aggravated offence

If the information has resulted in, will result in, or is likely to result in, the provision of a benefit that is, or may be, significantly detrimental to the interests of insured persons. The proposed penalty for this offence is 1000 penalty units

2

Underlying offence

Comparable to the offence in the *Criminal Code* for providing false or misleading information, but the penalty would be 300 penalty units. The *Criminal Code* offence for providing false or misleading information would continue to apply and would remain available if the circumstances warrant it.

3

Strict liability offence

Could provide for a graduated and proportionate response to providing false or misleading information. The penalty would not be more than 60 penalty units.

08 Information gathering about listed devices and products

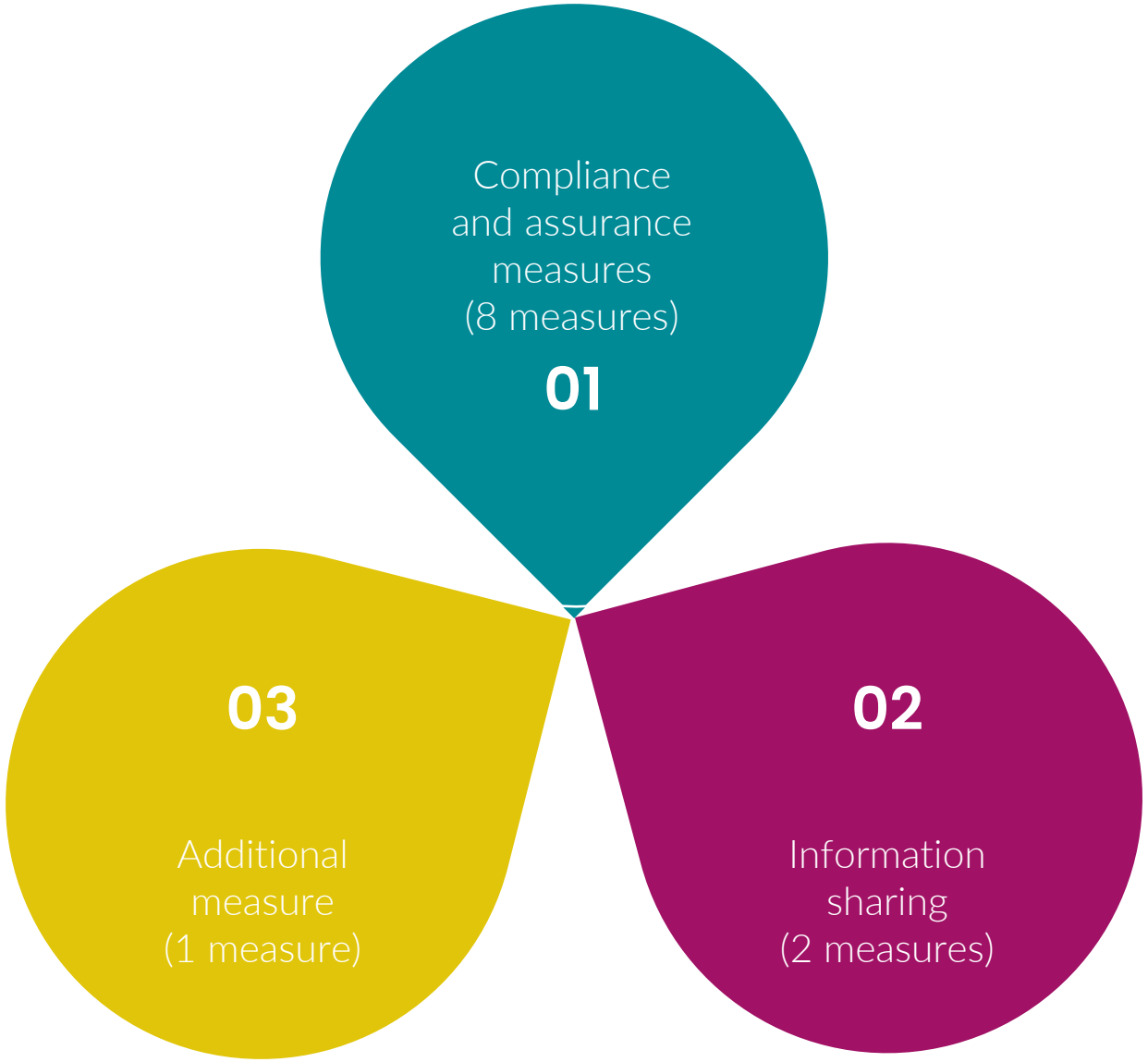
The PHI Act be amended to provide for a *notice to produce or attend* that would require a person to provide information or to attend to answer questions about:

- a listed device or product; or
- in connection with a listed device or product; or
- in a listing application.

A *notice to produce or attend* would only be issued to assist the effective administration of the PL (in relation to listed devices or products). The purpose of this notice is to continue to provide for informed decision making about listed devices and products based on the most contemporary and accurate information.

Non-compliance with a *notice to produce or attend* would be an offence and the privilege against self-incrimination would be overridden. However, a ‘use and derivative use’ immunity provision would be included to provide a degree of protection for the rights of individuals. This means there would be some degree of protection by constraining what the evidence can be used for.

3. Overview of the proposed measures for information sharing



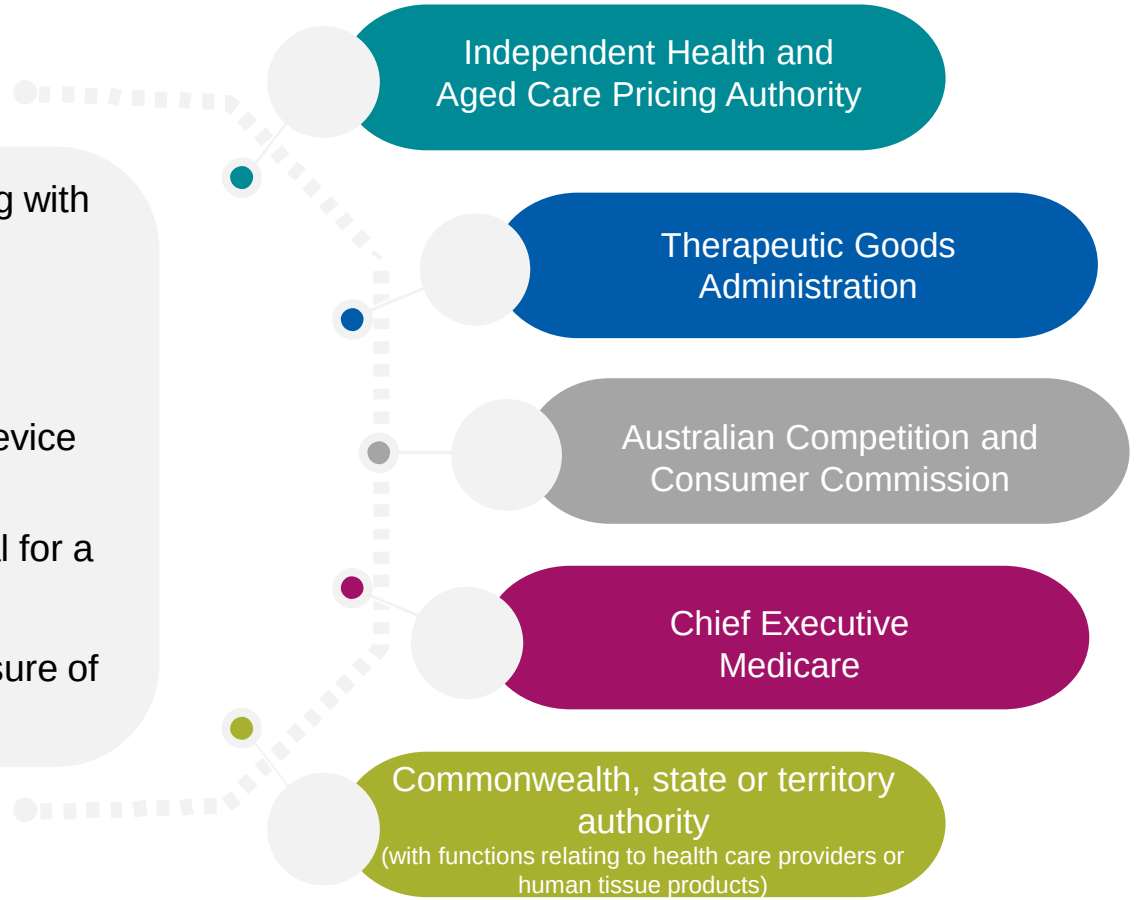
09 Disclosure of protected information

The *PHI Act* already provides for information sharing with some government agencies.

There is scope to share information with additional agencies for them to:

- perform their functions (such as approving a device or product)
- exercise powers (such as revoking an approval for a device or product).

The *PHI Act* would be amended to authorise disclosure of protected information with additional agencies.



Public summary documents

This proposed measure involves releasing information to the public about listed devices and products to promote public confidence in the PL. This information would be included in a *public summary document* (excluding confidential information).

The *public summary document* template would be completed by the applicant as part of the approved form for certain kinds of applications to the PL.

This proposed measure may not require any legislative amendments. If legislative amendments are required, then this may require the kinds of publicly available information to be specified in the *Private Health Insurance (Information Disclosure) Rules*.

4. Overview of the proposed additional measure

Objects of the PHI Act

Amend the PHI Act to include objects consistent with the proposed obligations (as current objects are focused on rules governing private health insurance).

An additional object may include:

regulating benefits payable under health insurance products to provide a clinically-effective, transparent, sustainable and predictable environment for private health insurers, health care providers (including the medical technology industry, hospitals and clinicians), policy holders and patients.

5. Proposed implementation timeline

01

Early 2024

Legislation for the information sharing measure, notice to produce and attend, and amendments to the objects of the PHI Act.

02

1 July 2024

Record keeping and notification **obligations** commence (no changes to compliance powers in PHI Act)

03

1 July 2025

Administrative sanctions (injunctions and enforceable undertakings; and removing a listing) commence for:
-non-compliance with record keeping and notification obligations
-providing false or misleading information

04

1 July 2026

Criminal offences and civil penalty provisions to apply for not complying with obligations, along with **infringement notices** that apply for strict liability offences

Public summary document introduced gradually from 1 July 2024, through changes to the application form.

6. Stakeholder impact

Stakeholder impact

Record keeping and notification measures (proposed measures 1, 2 and 3) could result in minor increases to regulatory costs.

Proposed measure for Public Summary Documents (proposed measure 10) could result in minor increases to implementation costs.

These costs could be mitigated if the measures are implemented to align with existing practices and/or regulatory measures, and are implemented in a staged manner.

No costs are expected for the other proposed measures.

7. Opportunity for stakeholders to ask questions or provide feedback on proposed measures

Getting in touch with us

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Post-listing reviews
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Compliance
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Australian Government
Department of Health and Aged Care