Australian Government

Department of Health and Aged Care

Prostheses List Reforms – Consultation Paper 7

Proposed measures for compliance, assurance and information sharing

Context for the consultation paper

Building on the previous reform activities, the Government has agreed to maintain the Prescribed List, with some improvements.

Following extensive consultation over recent years, this consultation paper will canvass views on proposed implementation of improvements to the Prescribed List. The Government considers these improvements are necessary to benefit consumers, because a number of reviews of the system have consistently found a high variance in the prices on the Prescribed List compared to prices paid in the public hospital system, with a limited ability for market forces to exert a downward pressure that would benefit consumers.

The Prescribed List is the primary mechanism governing the reimbursement for medical devices and human tissue products as part of the private health system in Australia.

The Prescribed List specifies a set benefit amount for listed medical devices and human tissue products. The Prescribed List benefit is payable to appropriately covered privately insured patients that receive a medical device or human tissue product as part of treatment, where there is a Medicare benefit payable for the medical service associated with the provision of the medical device or human tissue product. The treatment can be delivered in a private or public hospital, or in a hospital substitute setting.

The Private Health Insurance (Medical Devices and Human Tissue Products) Rules (**the MDHTP Rules**) is a legislative instrument made under the *Private Health Insurance Act 2007* (**PHI Act**), that sets up requirements in relation to the provision of a minimum price for medical devices and human tissue products. The Schedule to the MDHTP Rules is known as the Prescribed List.

Purpose

The purpose of this paper is to provide information about:

- proposed compliance and assurance measures; and
- proposed measures to promote information sharing among government agencies about medical devices and human tissue products included in the MDHTP Rules.

The Department is seeking feedback on the proposals, including any related evidence or data.

This paper builds on the information in the proposed Prescribed List Compliance Strategy, including the principles which govern the compliance, assurance and enforcement functions. Please read the information in that paper alongside the proposals in this paper.

The proposals in this paper support the Post-Listing Review Framework and represent a significant departure from some previous compliance proposals, as we have refined the proposed measures after taking into account comments and feedback from stakeholders.

There are many nuances with designing and implementing compliance measures, therefore the Department is keen to engage stakeholders directly on the proposed measures. The measures must be 'fit for the purpose of safeguarding the Prescribed List' and this may require some customising of the proposed measures based on input from stakeholders. This engagement is particularly important as the proposed measures could constitute new obligations for some stakeholders.

In considering the proposals, please note that legislative drafting of measures may mean that a different approach is necessary and may therefore differ slightly to the examples or suggestions in this paper.

Primary Legislation

The *Private Health Insurance Legislation Amendment (Medical Device and Human Tissue Product List and Cost Recovery) Act 2023* (PHI Amendment Act) introduces definitions of 'medical device' and 'human tissue product' into the PHI Act. The PHI Amendment Act commences on 1 July 2023.

The PHI Amendment Act removes current references to 'prosthesis' and 'prostheses' in the PHI Act and replaces them with 'medical device' and 'human tissue product'. The PHI Amendment Act also renames the 'Private Health Insurance (Prostheses) Rules' to the 'Private Health Insurance (Medical Devices and Human Tissue Products) Rules'. The Schedule to these rules is to be known as the 'Prescribed List of Medical Devices and Human Tissue Products (Prescribed List). The following table describes these changes.

Old Law terms	**New Law terms**
prostheses or prosthesis	medical device or human tissue product
Private Health Insurance (Prostheses) Rules (**Prostheses Rules**)	Private Health Insurance (Medical Devices and Human Tissue Products) Rules (**the MDHTP Rules**)
Prostheses List (Schedule to the Prostheses Rules)	Prescribed List of Medical Devices and Human Tissue Products (Prescribed List)(Schedule to the MDHTP Rules)
listed prosthesis (a kind of prosthesis listed in the Schedule to the Prostheses Rules)	listed device or product (a kind of medical device or human tissue product listed in the Schedule to the MDHTP Rules)

Current Legislative Context

As outlined in the Compliance Strategy, a number of obligations and expectations already apply to stakeholders (insurers, sponsors, hospitals) under private health insurance legislation. These include:

1. requirements in the *Therapeutic Goods Act 1989*, as they relate to conformity assessment, inclusion of medical devices and biologicals in the Australian Register of Therapeutic Goods (ARTG), compliance with the essential principles, as well as advertising, labelling, and product appearance;
2. the Australian Consumer Law (ACL) in Schedule 2 to the *Competition and Consumer Act 2010* (Cth), including in relation to misleading or deceptive conduct and remedies for loss or damage arising from misleading or deceptive conduct; and
3. the Criminal Code (Schedule to the *Criminal Code Act 1995* (Cth) (the Criminal Code) that may apply to providing false or misleading information to the Department.

The Department considers that there is scope to consider a more cooperative approach for safeguarding the Prescribed List with greater reliance on promoting a shared responsibility between government, sponsors, hospitals and insurers. The Department considers that this preventative approach would result in less emphasis on punitive measures, while recognising that punitive measures will still need to be available.

Policy Context

Prescribed List

The *Private Health Insurance Act 2007* (PHI Act) is about private health insurance (see section 3-1 of the PHI Act) and specifically, encouraging people to have private health insurance and rules governing private health insurance products.

Within this context, the Prescribed List represents a unique arrangement where applicants (who are not insurers) voluntarily apply to include a medical device or human tissue product in the Prescribed List and a benefit is specified for that device or product. A device or product is included in the Prescribed List if among other things, it demonstrates comparative clinical effectiveness and the benefit is proportionate to

the clinical effectiveness. The benefit that is derived is not necessarily the same as the price of that device.

Once included in the Prescribed List there are limited detailed requirements (other than the general measures above) that then apply. This leaves the ongoing maintenance of the Prescribed List to ad hoc reviews by the Department, or voluntary representations or applications from sponsors.

Currently, there is no need for sponsors to keep records relevant to a device or product in the Prescribed List, or to provide information to the Department when relevant new information becomes available ('relevant information' is discussed below). This means that there is limited scope for monitoring the clinical or cost effectiveness of listed devices and products and their appropriate use after they are included in the Prescribed List.

Safeguarding the Prescribed List

Recognising the limitations of the current approach of relying on general measures in other legislation, new measures are proposed to safeguard the integrity of the Prescribed List. The measures are intended to assure privately insured persons that devices and products in the Prescribed List remain safe, clinically effective and that the specified benefit for a device or product is proportionate to its clinical effectiveness. This includes ensuring that information in the Prescribed List about a device or product is correct and current.

The Department considers that this purpose would be achieved through:

- further encouraging sponsors to actively manage listed devices and products for which sponsors are responsible;
- continuing to provide for informed decision making about listed devices and products based on the most contemporary and accurate information;
- ensuring the Minister can respond to, and inform other relevant agencies of, issues or concerns about listed devices or products;
- increasing transparency about listed devices and products by publishing information about relevant items in a Public Summary Document (PSD).

Active Management of Listed Devices and Products

Modernising and improving the Prescribed List includes modernising and improving the management of the Prescribed List. Maintaining the Prescribed List is a shared responsibility between sponsors and government. The Prescribed List includes approximately 11,000 listed devices and products and the only practical and sustainable means of maintaining such a list is for sponsors and government to share the role of maintaining it.

Many sponsors have demonstrated their commitment to maintaining the Prescribed List through voluntarily applying to vary information about listed devices and products in the Prescribed List (e.g. updating sponsor names, changes to catalogue items etc). These actions have supported the maintenance of the Prescribed List. In addition, voluntary industry initiatives (memoranda of understanding) have ensured that specified benefits for medical devices have remained proportionate to their clinical effectiveness. These initiatives have also maintained the currency of the Prescribed List and delivered tangible benefit reductions for listed devices and products, and subsequently reduced costs for policy holders.

As part of actively managing listed devices and products, the Department is considering periodic benchmarking of benefits in the PL, including against public prices for the same or similar devices or products. This will help identify benefits that have grown beyond the rate of growth for similar devices and products in the public system. This information can then be used to identify potential post-listing review targets where the benefits appear to be superior for some devices and products that no longer demonstrate superior comparative clinical effectiveness.

To complement these voluntary initiatives, the Department is proposing specific legislative measures to further encourage <u>all</u> sponsors to actively manage their listed devices and products. These proposed measures are set out below.

Informed Decision Making

Informed decision making depends on correct information being readily available. This is necessary to provide for a proportionate, responsive and risk-based approach to maintaining the Prescribed List.

In practice, this means that certain information needs to be kept and provided when it is needed, so decisions can be made on the most contemporary and reliable information.

It also means that information must not be false or misleading. False or misleading information has the potential to seriously undermine public confidence in the Prescribed List. Specific legislative measures are therefore proposed to discourage the provision of false or misleading information, including in listing applications.

The exchange of information for informed decision making will need to be carefully managed as health information is sensitive information. Legislative changes will need to reflect this.

Legislative measures are proposed to provide for informed decision making about listed devices and products based on the most contemporary and accurate information.

Responding

Information collected through private health insurance legislation may be of relevance to other agencies, particularly in relation to information about listed devices and products and their use in Australia's health system. The community expects that government agencies work together to manage risks in Australia's health system. This means that information collected through private health insurance legislation should be able to be shared with other government agencies so that 'government' generally can respond to issues or concerns about the use of listed devices or products.

Legislative measures are therefore proposed to ensure the Minister can respond to, and inform other relevant government agencies of, issues or concerns about listed devices or products. There is also a direct benefit to applicants if they only need to submit information once.

Principles

In developing the proposed measures, the Department has considered a number of references. These include:

- the Health Regulatory Policy Framework; and
- 'A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers'.

To guide the further development of the proposed measures, the Department has developed and used the following principles:

- to implement preventative measures with the intention of 'assuring' compliance and reducing the need for punitive measures
- to transparently specify the obligations for entities, so responsibilities are clear and apply equally to all relevant entities
- to provide for proportionate responses to suspected non-compliance, based on accurate information that is readily available
- 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
- 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 (rather than new measures being an 'add on' to current regulatory requirements)
- to constrain proposed measures to listed devices or products in the Prescribed List, or circumstances in connection with listed devices or products in the Prescribed List, to minimise impacts on other provisions in the PHI Act, including regulatory impacts.

Proposed Measures

The proposed measures are in three parts:

- Proposed compliance and assurance measures.
- Proposed information sharing measures.
- Proposed additional measures.

In the proposed measures there are some terms used and the following represents a key or glossary for these terms.

Applicant	person who has applied to list a medical device or human tissue product in the Prescribed List (see 'sponsor' below)
Approved form	form that meets the requirements in Section 333-10 of the PHI Act
Guide	A Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers (Dated September 2011 and published 9 January 2013)
Human tissue product	has the meaning in the PHI Act (as amended)(not the same as in the *Therapeutic Goods Act 1989*)
Information	includes a statement, notice, application or document
Listed device or product	medical device or human tissue product listed in the Prescribed List and includes: o the amounts of benefits (minimum and if relevant maximum); and o the method for working out the amount of benefits (minimum and if relevant maximum); and o any conditions for the provision of that device or product
MDHTP Rules	Private Health Insurance (Medical Devices and Human Tissue Products) Rules made for the purposes of item 4 of the table in subsection 72 1(2) under the power in item 4 of the table to subsection 333-20(1) of the PHI Act (as amended)
Medical device	has the meaning in the PHI Act (as amended)(not the same as in the *Therapeutic Goods Act 1989*)
PHI Act	*Private Health Insurance Act 2007*
Regulations	regulations that may be made for the *Private Health Insurance Act 2007* (PHI Act) (section 333-30 of the PHI Act)
Sponsor	Sponsor, for a listed device or product, means the person who made the listing application as a result of which the device or product was listed in MDHTP Rules (i.e. the person responsible for a listing of a device or product in the PL).
TG Act	*Therapeutic Goods Act 1989*

Proposed Compliance and Assurance Measures

The proposed compliance and assurance measures represent 'proposed policy'. The focus of these measures is the policy and purpose of the measures, rather than the 'tool' or enforcement power for giving effect to the policy. In some cases, this enforcement power is included in the proposal (for example, the proposed measure for 'offences' for providing false or misleading information), as this may assist stakeholders in considering the policy proposal.

In many cases, the appropriate measure for giving effect to the proposed policy may simply be education. Please see the proposed Prescribed List Compliance Strategy for more information about this and the proposed enforcement model.

In some cases, specific legislated enforcement powers may be necessary for transparency and to ensure an adequate response to alleged non-compliance can be implemented. In other regulatory schemes, these enforcement powers can take different forms, including:

- Injunctions
- Enforceable undertakings
- Infringement notices
- Administrative sanctions like cancelling licences etc
- Civil proceedings
- Criminal proceedings

Some of these kinds of powers are already provided for in the PHI Act but only currently apply to insurers (not sponsors or hospitals).

In considering the proposed compliance and assurance measures, stakeholders are asked to also consider if they would support enforcement powers such as injunctions, enforceable undertakings or infringement notices being available to support the proposed measures. These enforcement powers would provide more flexibility in introducing what could be considered new requirements for some stakeholders. If these measures were supported then they would need to be legislated in the PHI Act. They could not be provided for in delegated legislation (like 'Rules'), although the detail about specific requirements (like record keeping) could be specified in delegated legislation.

While compliance and assurance measures apply for most regulatory schemes, there is always a degree of 'customisation' to reflect the nature of the particular regulatory scheme. This customisation includes considering the regulated entities in the scheme, contemporary drafting practice and contemporary Parliamentary scrutiny principles. This means that it is not always possible or desirable to use 'provisions' from other regulatory schemes when developing new compliance and assurance measures.

With that in mind, the Department has proposed compliance and assurance measures that are considered to be 'fit for the purpose of safeguarding the Prescribed List'. The proposed measures have been developed with the intention of imposing new obligations in a way that would or may be familiar to stakeholders. However, as stated above, they represent 'proposed policy' for the purposes of engaging stakeholders about compliance and assurance measures, with the view that the measures may need to be customised for the purpose of safeguarding the Prescribed List.

1. Proposed measures for sponsors

The PHI Act be amended to introduce new record keeping and notification obligations for sponsors.

These obligations would require a sponsor to:

a. make and keep records about a listed device or product with the kinds of information to be specified in the MDHTP Rules (see below for examples);
b. provide records about a listed device or product with the kinds of records to be specified in the MDHTP Rules (see below for more information), including when these records are to be provided by the sponsor (so the obligation is not overly onerous);
c. provide 'relevant information' about a listed device or product (see 'relevant information' below);
d. provide correct information about a listed device or product if incorrect information has previously been provided by the sponsor;
e. ensure records made, kept or provided about a listed device or product are in the approved form;
f. provide any other information-related obligations about listed devices or products that are specified in the MDHTP Rules.

The purpose of these obligations is 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. The obligations are intended to further encourage sponsors to actively manage listed devices and products for which sponsors are responsible.

Maintaining the Prescribed List is a shared responsibility between sponsors and government and the proposed new obligations for making, keeping and providing records and other information are intended to further that objective and promote public confidence in the Prescribed List.

1.1 Implementation of these obligations

Should this proposed measure proceed, the means of implementing these obligations will need to be discussed with the Office of Parliamentary Counsel. One possible means of implementing this measure would be to introduce conditions of listing (or a similar obligation that would operate in a manner that is similar to conditions for inclusion in the ARTG – see section 41FN of the TG Act). These 'conditions of listing' would be separate and completely independent from the current conditions for the provision of a listed item (See item 4 of the table to subsection 72-1(2) of the PHI Act).

These conditions of listing could operate like the conditions on declarations of hospitals in Division 121 of the PHI Act. The intention is to implement the obligations in a manner that is familiar to sponsors and consistent with the current regulatory approach in the PHI Act for other regulated entities.

Alternatively, another means of implementing this policy would be to specify these obligations in the MDHTP Rules and require compliance with these obligations through a criminal offence (in the PHI Act or regulations).

The Department requests comment from stakeholders on the concept of introducing 'conditions of listing' as a means on introducing new obligations on sponsors, particularly if sponsors would readily differentiate these 'conditions of listing' from the current 'conditions for the provision of a listed device or product'.

1.2 Kinds of records to be specified in the MDHTP Rules

It is anticipated that the kinds of records to be kept, made and provided would include:

- clinical records in connection with the provision (use) of a listed device or product that are sufficient to demonstrate the clinical effectiveness of the listed device or product, including a comparison of the clinical effectiveness for the listed device or product with a medical device or human tissue product or treatment that could be used instead of the listed device or product; and
- records of the costs of the provision of a listed device or product, as well as costs associated with the use of the listed device or product in other markets both overseas or within Australia; and
- records that are sufficient to demonstrate that the cost of the listed device or product is proportionate to the clinical effectiveness of the listed device or product, when compared with a

medical device or human tissue product or treatment that could be used instead of the listed device or product; and

- a specified period of time that specified records are to be kept.

For this measure, the Department requests comment from stakeholders on whether these records are substantially different from the records that sponsors already keep.

1.3 Relevant information

For the proposed measures, 'relevant information' would be information that could be considered 'adverse' for a listed device or product and include:

- information that a listed device or product may no longer meet the listing criteria (e.g. no longer included in the ARTG)
- information in an application, statement, notice or document provided to the Department that was incomplete or incorrect, irrespective of whether the application has been decided or not
- information that the MDHTP Rules contain incorrect or incomplete information about a listed device or product
- information that contradicts either:
    - information contained in the MDHTP Rules about a listed device or product; or
    - information previously provided to the Department about a listed device or product.
- other information of a kind specified in the MDHTP Rules

2. Proposed measures for hospitals

The PHI Act be amended to require hospitals to make, keep and provide records about listed devices and products. These obligations would require a hospital to:

a. make and keep records about listed devices and products with the kinds of records to be specified in the Private Health Insurance (Health Insurance Business) Rules (the current relevant rules for conditions for these hospital declarations);
b. provide records about listed devices and products with the kinds of records to be specified in the Private Health Insurance (Health Insurance Business) Rules, including when these records are to be provided by the hospital;
c. provide 'relevant information' (see 'relevant information' above);
d. provide correct information if incorrect information has previously been provided by the hospital;
e. ensure records made, kept or provided must be in the approved form;
f. any other obligations that could be specified in the Private Health Insurance (Health Insurance Business) Rules.

In addition to keeping records about listed devices and products, hospitals would also be required to maintain a register of non-financial gifts and benefits that they received throughout the financial year. The gifts and benefits would only be in relation to the provision and procurement of devices and products listed on the Prescribed List and would then be submitted to the Department on an annual basis.

Hospitals would only be required to report their gifts and benefits if that gift or benefit was a device or product on the Prescribed List. Any gift or benefit received by a hospital that is not an item on the Prescribed List, such as a monetary benefit, would not need to be reported.

The purpose of reporting non-financial benefits is not to impinge on normal commercial arrangements, such as receiving discounts for items bought in bulk, but to reduce the number of claims for benefits for items on the Prescribed List when there was never any outlay for the device or product.

A scenario would be if a sponsor incentivised a hospital to supply their listed item over a competitor's by offering them a free supplementary item which was also listed on the Prescribed List. But when it came to

claiming the Prescribed List benefit from the insurer, the hospital claimed a benefit for both items, even though there was never any outlay for the second item.

The proposed measures would require a hospital to report any non-financial benefit they received that was a device or product listed on the Prescribed List. Information they may be required to provide about each transaction could include:

- Date of the transaction
- Name of the hospital in receipt of the gift or benefit
- Name of the organisation offering the gift or benefit
- Description of the gift or benefit
- Reason for the offer
- Estimated value
- Prescribed List billing codes

All items on the Prescribed List that were received with no expenditure by the receiving hospital would be expected to be reported.

There is no proposal to include any sanctions or penalties regarding any gifts or benefits, however there would be an obligation to provide the information each year and there would be penalties for giving false or misleading information as described in Proposed Measures 6 and 7 below. The Department may also decide to publish the annual reports each year, and/or an analysis of the annual reports.

These obligations would only apply in relation to listed devices and products. It may already be possible to specify these obligations in the Private Health Insurance (Health Insurance Business) Rules but legislating these requirements in the PHI Act would 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 (see Division 121 of the PHI Act) include the obligations above.

The purpose of these obligations is to ensure that current and accurate information is available to demonstrate that devices and products in the Prescribed List remain safe, clinically effective, that the specified benefit for a device or product is proportionate to its clinical effectiveness, and to promote transparency behind claims on the Prescribed List.

2.1 Kinds of records to be specified in the Private Health Insurance (Health Insurance Business) Rules

It is anticipated that the kinds of records to be kept, made and provided by a hospital would include:

- clinical records in connection with the provision (use) of a listed device or product; and
- records of the costs of the provision of a listed device or product; and
- details about non-financial benefits received that are a listed device or product; and
- a specified period of time that records are to be kept.

2.2 Relevant information

For the proposed measures, 'relevant information' would be:

- information that a listed device or product may no longer meet the listing criteria (e.g. no longer included in the ARTG)
- information in a statement, notice or document provided to the Department that was incomplete or incorrect
- information that the MDHTP Rules contain incorrect or incomplete information about a listed device or product
- information that contradicts either:

- information contained in the MDHTP Rules about a listed device or product; or
- information previously provided to the Department about a listed device or product.

- other information of a kind specified in the Private Health Insurance (Health Insurance Business) Rules

3. Proposed measures for insurers

Amend the PHI Act to provide that the Private Health Insurance (Complying Product) Rules may specify record keeping and notification requirements consistent with the requirements in Proposed Measure 1 and 2 above but only for records that would be relevant for insurers to keep and provide. These obligations would include the making, keeping and providing of records about listed devices and products, as well as the provision of relevant information (see above). These obligations would be specified in the Private Health Insurance (Complying Product) Rules.

It may already be possible to specify these obligations in the Private Health Insurance (Complying Product) Rules but legislating these requirements in the PHI Act would provide for more transparency.

4. Specific offences applicable to insurers and health care providers

It is proposed that offences for refusing or failing to comply with the obligations above NOT be included in the PHI Act, as this would be inconsistent with the current approach for hospital declaration conditions in Division 121 of the PHI Act.

However, it is recognised that that the PHI Act already includes such offences for insurers in relation to refusing or failing to comply with record keeping. For this reason, it is proposed that 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.

This proposed measure would allow the regulations made under the PHI Act to also prescribe record keeping and information requirements that could be specified in the rules made under the PHI Act. This measure would also provide that the regulations may prescribe offences not exceeding 20 penalty units for refusing or failing to comply with a prescribed requirement in the regulations. The combined effect of these measures would be to provide for the record keeping and notification obligations and the criminal penalty to be co-located in the one legislative instrument.

These regulations would only be made if administrative sanctions (see below) were found to be insufficient or inappropriate for achieving compliance with the record keeping and notification obligations. This policy would operate in practice by repealing any record keeping or notification obligations from the relevant ‘Rules’ and prescribing both the record keeping and information obligations and any offences in the regulations. Regulations may prescribe offences but ‘Rules’ cannot specify offences.

This measure would only apply for records and notification of information about listed devices and products.

In the event of an inconsistency between a requirement in any rules or the regulations then the matter in the regulations would prevail.

This measure may never be needed (and regulations may not be required) if substantial compliance with the measures above is demonstrated. However, it provides a safeguard for the future that would allow criminal offences to be prescribed should these be considered necessary.

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 new record keeping and notification obligations and criminal offences for not complying with these obligations.

5. Administrative sanctions for health care providers

5.1 Sponsor

The PHI Act be amended to provide for the removal of a listed device or product from the MDHTP Rules if the sponsor refuses or fails to comply with the record keeping and notification obligations in Proposed Measure 1 above. This would be subject to Administrative Appeals Tribunal review.

5.2 Hospital

The PHI Act be amended to provide that a declaration for a hospital may be revoked if the holder of the declaration refuses or fails to comply with the record keeping and notifications obligations in Proposed Measure 2 above.

The proposed new power to revoke a declaration would only apply to the obligations in Proposed Measure 2 above. Revoking a declaration of a hospital is already subject to Administrative Appeals Tribunal review and this proposed measure would not change that.

These administrative sanctions are necessary to ensure that health care providers comply with the proposed obligations. These measures should be legislated in the PHI Act for transparency and the availability of Administrative Appeals Tribunal review would also be legislated.

This measure may be implemented more proportionately through providing for injunctions or enforceable undertakings for not complying with the obligations, rather than through revoking a declaration or removing a listed device or product. Stakeholders may wish to comment on the use of enforcement powers such as injunctions and enforceable undertakings, recognising that the wider availability of these measures would need to be legislated for in the PHI Act.

Stakeholders may also wish to comment on whether these administrative sanctions should be subject to additional considerations before removing a listed device or product or before revoking a hospital declaration. For example, should any detriment to insured persons be considered before removing a listed device or product or revoking a hospital declaration?

6. False or misleading information - administrative sanctions

6.1 Sponsor

The PHI Act be amended to provide for the removal of a listed device or product from the MDHTP Rules if the sponsor provides false or misleading information about the listed device or product. The exercise of this specific power to remove a listed device or product from the MDHTP Rules would be subject to Administrative Appeals Tribunal review.

Currently, a listed device or product could be removed if false or misleading information was provided and the exclusion of this information meant that the listed device or product no longer met the requirements for listing (e.g. no longer clinically effective). However, this current approach would require a complete new evaluation of the listed device or product with no means of imposing the costs of this new evaluation on the sponsor. This means that other sponsors would be cross-subsidising this activity. The proposed measure addresses this by providing for the removal of a listed device or product if false or misleading information was provided, without the need to conduct a complete new evaluation.

6.2 Hospital

The PHI Act be amended to provide that a declaration for a hospital may be revoked if the holder of the declaration provides false or misleading information about a listed device or product. The exercise of this power would be subject to Administrative Appeals Tribunal review.

The administrative sanctions above are necessary to ensure that health care providers do not provide false or misleading information about listed devices or products. These measures should be legislated in the PHI Act for transparency and the availability of Administrative Appeals Tribunal review would be legislated.

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.

Stakeholders may wish to comment on the use of injunctions or enforceable undertakings, recognising that the availability of these measures would need to be legislated for in the PHI Act.

Stakeholders may also wish to comment on whether these administrative sanctions should be subject to additional considerations before removing a listed device or product or before revoking a hospital declaration. For example, should any detriment to insured persons be considered before removing a listed device or product or revoking a hospital declaration?

7. False or misleading information – criminal sanctions

Giving false or misleading information is a serious offence. The Criminal Code (Schedule to the *Criminal Code Act 1995* (Cth)) currently applies to providing false or misleading information to the Department. Recognising the seriousness of providing false or misleading information, 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; or
- in a listing application (an application to list a medical device or human tissue product in the MDHTP Rules).

These provisions would only apply to persons that provide information about a listed device or product. The measures would only apply for information that is false or misleading in a material particular. That is, the information is false or misleading and the information is relevant to determining whether the medical device or human tissue product is clinically effective and that the specified benefit for the device or product is proportionate to its clinical effectiveness.

The aggravated offence would only apply 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. This mirrors the aggravated offence in the *Private Health Insurance (Prudential Supervision) Act 2015*. The proposed penalty for this offence would be 1000 penalty units (equal to the highest penalty currently imposed under the PHI Act – see section 84-1).

The underlying offence would be comparable to the offence in the Criminal Code for providing false or misleading information but the penalty would be higher to reflect the seriousness of providing false or misleading information about a listed device or product. A penalty of the order of 300 penalty units is proposed. This amount is between the maximum penalty that can currently be imposed under the PHI Act (1000 penalty units) and the highest penalty for a strict liability offence in the Guide to Framing Commonwealth Offences, Infringement Notices and Enforcement Powers (the Guide) (60 penalty units). The Criminal Code offence for providing false or misleading information would continue to apply and would remain available if the circumstances warranted it. For this reason, the Department requests comment on the value of a separate underlying offence for providing false or misleading information, given the availability of the current offences in the Criminal Code.

The strict liability offence could provide for a graduated and proportionate response to providing false or misleading information and the penalty would not be more than 60 penalty units (as per the Guide). The Department requests comment on the value of a separate strict liability offence for providing false or misleading information, given the current offences in the Criminal Code.

These penalties are different from those that may apply under other legislation because they need to reflect the current penalties in the PHI Act. Providing false or misleading information has the potential to seriously undermine public confidence in the Prescribed List and the proposed measures are intended to ensure that appropriate regulatory action can be taken against persons that wish to engage in such activity.

8. Information gathering about listed devices and products – persons with information about listed devices or products

The PHI Act be amended to provide for a 'notice to attend or produce' 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.

This kind of 'notice to produce or attend' provision is a legislative provision that allows an agency to require a person to produce information or documents, or to appear before an officer of an agency at a hearing to answer questions. This is a common mechanism used to assist in the administration of Commonwealth legislation (see the Guide).

A notice to produce or attend would only be issued where the issuer (a Senior Executive Service Officer) reasonably believes that the person required to produce documents or information or to answer questions has custody or control of documents, information or knowledge, which will assist the effective administration of the Prescribed List (in relation to listed devices or products).

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 (but not bodies corporate). See the Guide for more information about these kinds of notices.

This kind of notice already applies for insurers under the PHI Act (see Division 197) and sponsors would be familiar with similar provisions in the TG Act (for example, Part 4-8 in Chapter 4 of the TG Act). A contemporary example of a provision of this kind can be found in Part 4A of the *Dental Benefits Act 2008*.

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, which may only be available to the person to which the notice would be issued.

Proposed Information Sharing Measures

9. Disclosure of Protected Information

It is proposed to allow the sharing of information with nominated entities in prescribed circumstances.

Information about a listed device or product is likely to be 'protected information' and the disclosure of that information is dealt with in Division 323 of the PHI Act. Section 323-5 already authorises the sharing of information for official duties with APRA, the Private Health Insurance Ombudsman and agencies administering 'medicare programs'. Division 323 also provides for further disclosure to be authorised if that is in the public interest.

While Division 323 of the PHI Act already provides for information sharing with some government agencies, there is scope to share information with additional Commonwealth, State and Territory agencies so that these agencies can use the information to perform their functions (such as approving a medical device) and exercise powers (such as revoking an approval for a device). It is appropriate that this policy be legislated in the PHI Act, even though the PHI Act may already provide a means for sharing information with other agencies where that is in the public interest.

The agencies would include those agencies that regulate the:

- supply of a listed device or product (e.g. TGA); or
- treatment with a listed device or product (e.g. by health care providers); or
- benefits paid for treatment with a listed device or product.

The authority in Division 323 could be extended to include additional relevant government agencies and this would involve amending the PHI Act to authorise disclosure of protected information:

- to the Independent Health and Aged Care Pricing Authority (part of the Department of Health and Aged Care) to enable a person to perform functions under a provision of the *National Health Reform Act 2011* (Independent Health and Aged Care Pricing Authority or the Australian Commission on Safety and Quality in Health Care)
- to the Therapeutic Goods Administration (Part of the Department of Health and Aged Care) to enable a person to perform or exercise a duty, function or power under the *Therapeutic Goods Act 1989*

- to the ACCC to enable a person to perform or exercise a duty, function or power under the *Competition and Consumer Act 2010*
- to the Chief Executive Medicare to enable a person to perform functions or exercise powers under the *Human Services (Medicare) Act 1973* (potentially amending 323-5)
- to an authority of the Commonwealth, a State or a Territory that has functions relating to health care providers but only if the disclosure is made for the purpose of enabling a person to perform or exercise duties, functions or powers under a Commonwealth, State or Territory law that deals with complaints about health care providers or regulates, licences, registers, accredits or otherwise approves health care providers (potentially amending section 323-5)
- to an authority of the Commonwealth, a State or a Territory that has functions relating to human tissue products but only if the disclosure is made for the purpose of enabling a person to perform or exercise duties, functions or powers under a Commonwealth, State or Territory law that regulates, licences, registers, accredits or otherwise approves human tissue products

10. Public Summary Documents

It is proposed to allow for certain information about listed devices and products to be included in a 'Public Summary Document'. The publication of this information is proposed to be introduced gradually by requiring applicants to complete a Public Summary Document template. This would be completed by the applicant as part of the approved form for certain kinds of applications to include a medical device or human tissue product in the MDHTP Rules.

This may not require any legislative amendments and is included in this document for completeness.

This proposed measure involves releasing information to the public about listed devices and products to promote public confidence in the Prescribed List. The information would not include information provided to the Department in confidence, and the applicant can control and ensure this as part of completing the proposed Public Summary Document template in the approved form for the application.

If legislative amendments are required to implement this policy then this may require the kinds of publicly available information to be specified in the Private Health Insurance (Information Disclosure) Rules as information that may be released to the public. These rules could be updated incrementally to reflect the kinds of information to be made public (i.e. the kinds of medical devices for which a Public Summary Document would be appropriate). The relevant provisions could, for example, mirror subsections 61(5C) and 61(5D) of the *Therapeutic Goods Act 1989*.

Proposed Additional Measures

11. Objects of the PHI Act

The proposed measures above may mean it would be appropriate to extend the objects of the PHI Act, as these measures impose obligations on persons other than insurers. Reflecting this, it may be appropriate to amend section 3-1 of the PHI Act to include objects consistent with the new obligations (noting that the current objects are focussed 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 [insured persons].*

Implementation

The proposed measures could be implemented in an incremental manner over a period of time, for example:

1. From Royal Assent of the legislation for compliance, assurance and information sharing measures, the measures for information sharing (Proposed Measure 9), the notice to produce or attend (Proposed Measure 8) and amendment of the objects (Proposed Measure 11) could commence and apply.
2. From 1 July 2024 (when the levy commences), the obligations for record keeping and notification obligations (Proposed Measures 1, 2 and 3) could apply without any change to compliance powers in the PHI Act.
3. From 1 July 2025 – administrative sanctions (injunctions and enforceable undertakings) for not complying with record keeping and notification obligations would apply (Proposed Measures 1, 2 and 3). This would mean that these administrative sanctions would not commence until 12 months after the commencement of the record keeping and notification obligations. At the same time, administrative sanctions would commence for removing a listing for either not complying with record keeping and notification obligations or for providing false or misleading information (Proposed Measures 5 and 6).
4. From 1 July 2026 – providing for criminal offences and civil penalty provisions to apply for not complying with obligations, along with infringement notices that could apply for strict liability offences (Proposed Measures 4 and 7).
5. Proposed measure 10 would be introduced administratively through changes to the approved forms for applications, and this would occur incrementally from 1 July 2024.

Anticipated stakeholder impact

In summary, Proposed Measures 1, 2 and 3 are expected to increase regulatory costs, specifically for the record keeping and notification measures. Proposed measure 10 (Public Summary Documents) may also have implementation costs. The Department considers that these costs can be significantly mitigated if the measures are implemented to align with existing regulatory measures and implemented in a graduated manner.

No costs are expected for the other proposed measures.

Next Steps

The Department would like to engage stakeholders directly on these proposed measures. The measures must be ‘fit for the purpose of safeguarding the PL’ and this may require some customising of the measures with stakeholders. This will ensure that the policy is clear and the legislative drafting can give effect to the policy.

The Department will consider comments provided as part of this consultation, as a basis for further engagement with stakeholders about specific details for compliance, assurance and information sharing measures.

Any subsequent proposed measures would need to be considered by Government and if supported, would be included in further legislative amendments for consideration by the Parliament.

What we invite you to do

We ask that stakeholders provide feedback on the proposed measures and any ideas they have to address the issues via the consultation hub. This feedback will be used to inform any further refinement of the measures as well as subsequent consultation.

The Department intends to publish the submissions so stakeholders should not include commercial in confidence information or should put it under a separate attachment, noting it may still be accessible under FOI processes.

Please consider the questions below and provide your responses, and any other comments about the matter in this consultation paper.

1. Do you support the concept of a ‘shared responsibility’ for safeguarding the Prescribed List? If not then why not?
2. Do you consider that the role of insurers, sponsors and hospitals in safeguarding the Prescribed List needs to be expanded? If so, what additional obligations do you consider are necessary and why?
3. Do you agree with the policy principles used for developing the proposed measures?
4. What additional resources would be useful to consider in developing the proposed measures?
5. What are the likely impacts of each proposed measure from your perspective?
6. How might these impacts be mitigated?
7. What do you think of the concept of introducing ‘conditions of listing’ as a means of introducing new obligations on sponsors? In your view, is it possible to readily differentiate these ‘conditions of listing’ from the current ‘conditions for the provision of a listed device or product’?
8. One point that stakeholders may wish to comment on would be the use of different ‘Rules’ for specifying the record keeping and notification requirements in Proposed Measures 1, 2 and 3. Should these requirements for listed devices and products be specified in the MDHTP Rules for all stakeholders, or should different Rules include these obligations?
9. Should additional considerations apply before removing a listed device or product or revoking a hospital declaration for providing either false or misleading information or not complying with record keeping obligations? For example, should any detriment to insured persons from removing a listed device or product or revoking a hospital declaration be considered?
10. Should the offences in the Criminal Code continue to be relied on as the only means for dealing with false or misleading information?
11. In Proposed Measure 7, what is the value of a new strict liability offence and a new underlying offence for providing false or misleading information when the Criminal Code already applies?
12. Should additional compliance measures be considered? Please provide the basis for these additional measures.
13. Do you think there are other agencies that should be authorised for disclosure of protected information? For example, professional associations for health care providers?
14. 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?
15. 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?
16. What do you think of the proposed incremental implementation of the proposed measures?
17. 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?
18. Do you consider that disqualifying criteria should apply for sponsors of listed devices or products in that if the sponsor has been convicted of a criminal offence then should the sponsor be disqualified from being a sponsor for a listed device or product?