



Prostheses List Compliance Strategy

Safeguarding the Prostheses List

PROPOSED
For PL stakeholder consultation

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This document is intended to provide additional guidance to stakeholders about the approach we take to compliance, assurance and enforcement activities in support of the Prostheses List and program. These functions are carried out in accordance with statutory requirements and this strategy cannot override those requirements. It does not constitute legal advice.

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Introduction

The Australian health system operates under a mixed model of private and public health care with private health insurance (PHI) and private hospitals playing an important role. Australians with PHI may choose to receive treatment as private patients in either private or public hospitals. For privately insured patients with appropriate health cover, private health insurers are required to pay set benefits for prostheses (medical devices and biologicals) when they are provided in prescribed circumstances.

The *Private Health Insurance (Prostheses) Rules* is a legislative instrument made under the *Private Health Insurance Act 2007*. The Schedule of the *Private Health Insurance (Prostheses) Rules* is known as the Prostheses List (PL).

The PL established in 1985, sets the minimum benefit private health insurers must pay to hospitals for a surgically implanted prosthesis received by a private patient in a privately insured episode of hospital treatment. Examples of prostheses are joint replacement devices – for hips and knees; cardiac implantable electronic devices – such as pacemakers; and human tissue items – like bone or bone fragments.

Increasing medical costs, increasing utilisation of health services (particularly by older people and people with chronic disease) and declining participation rates (particularly by younger Australians) is challenging the affordability and long-term sustainability of the PHI sector. The Australian Government (the Government) recognises the important role that medical devices play in the overall health of Australian patients and the need to maintain a stable, sustainable and innovative medical device sector.

In 2019-20, more than 3.1 million prostheses on the list were supplied at a cost – to private health insurers – of approximately \$2.1 billion. Expenditure on prostheses accounts for 14 per cent of PHI hospital benefits paid annually. During the June 2021 quarter, insurers paid \$588 million for prostheses items. Total benefits paid for prostheses increased by 12.3% in June 2021 compared to March 2021. The cost of prostheses on the PL has been identified as a factor in the rising cost of health insurance premiums for consumers.

As part of the PL reforms, the Government is committed to ensuring privately insured patients have access to safe, clinically appropriate and cost-effective prostheses, chosen by their clinicians. The Therapeutic Goods Administration (TGA) is responsible for regulating the quality, safety and performance of medical devices, including prostheses, in Australia. The Minister for Health and Aged Care, and the Department of Health and Aged Care (the Department) may take advice on the comparative clinical effectiveness and cost-effectiveness of prostheses from the Prostheses List Advisory Committee (PLAC), prior to their listing on the PL. The arrangements for including products on the PL help to ensure that benefits paid by insurers are relative to reference pricing. It is an avenue for reimbursement, in that the benefit shown on the PL is the amount payable by private insurers for the prosthesis.

Prostheses List Compliance

The Government, the public, and health professionals expect that medical device companies (sponsors and manufacturers), private hospitals and private health insurers understand and adhere to legislated rules and policy requirements that govern the benefit price settings of the PL.

These rules include listing criteria along with clinical and cost-effectiveness assessments for listing products (medical devices and biologicals) on the PL. This helps ensure that every product is considered in the same way, and that the recommendations for listing are consistent, fair and equitable, thus ensuring privately insured patients have access to clinically appropriate and cost-effective prostheses.

The Department recognises that most stakeholders maintain high standards and adhere to their obligations through simple measures such as:

- proactively educating themselves about the rules and requirements, using the range of services and resources provided by the Department
- presenting medical devices for listing that have been included on the Australian Register of Therapeutic Goods (ARTG)
- ensuring that listing applications are for eligible medical devices
- creating and retaining clinical, cost and administrative records as they relate to medical devices at the time of the application for listing, and throughout the time the product is listed.
- retaining oversight of regulatory requirements, approvals, benefit pricing, usage and clinical effectiveness, and remediating any errors or anomalies
- proactively contacting the Department if they make or discover errors or anomalies with the listed medical device(s) and biologicals
- ensuring their commercial arrangements for the supply of medical devices listed on the PL do not result in out-of-pocket expenses for consumers
- actively monitoring the comparative prices for medical devices in both the Australian public hospital market and comparable international markets to ensure the PL benefits are appropriately aligned.

Purpose

The Prostheses List Compliance Strategy (the Strategy) identifies the principles which govern the Department's compliance, assurance and enforcement functions, and the associated priorities in support of the PL. It aligns with the [Department's Corporate Plan](#) and [Fraud and Corruption Control Plan](#).¹

The Strategy also sets out the compliance obligations within the context of the legislative instruments, and the steps the Department may take where there are concerns about non-compliance activities.

The Strategy is applicable to all stakeholders participating in the PL (PL stakeholders) arrangements – such as Hospitals and Day Clinics, clinicians, manufacturers and sponsors of medical devices and biologicals, and private health insurers.

¹ The departmental plans are updated annually.

Principles of regulator best practice

The Strategy guides the Department to monitor and enforce compliance and assurance through these key principles.²

1. **Continuous improvement and building trust** – adopt a whole-of-system perspective, continuously improving performance, capability and culture to build trust and confidence in Australia's regulatory settings.
2. **Risk based and data driven** – manage risks proportionately and maintain essential safeguards while minimising regulatory burden and leveraging data and digital technology to support those they regulate to comply and grow.
3. **Collaboration and engagement** – be transparent and responsive communicators, implementing regulations in a modern and collaborative way.

The Department is committed to a stewardship approach to the administration of the PL. Thus it is designed to be fit-for-purpose, periodically monitored, and implemented in a way that it safeguards to the integrity of the PL while reducing the regulatory burden.

Compliance priorities

Four areas of priority that seek to safeguard the integrity of the PL are:

- **Benefit setting and claiming** – relative to the public hospital sector and comparable international markets
- **Scope and definition** – maintain the integrity of the PL by ensuring eligibility requirements are met
- **Consolidation of the PL** – structure simplified and aligned to clinical application to provide transparency and ease of use and navigation
- **Listing conditions** – intended use and cost-effectiveness.

In taking actions to encourage, strengthen and enforce compliance with the PL system – and in alignment with the Department's compliance principles and legislative requirements – the Department will always prioritise the interests of patients and the integrity of the private health benefits system.

This includes **prioritising action to address (inappropriate) practices** that:

- distort the benefit price settings
- encourage artificial listing structures
- establish benchmark benefit pricing for discontinued or dormant devices (i.e. product substitution)
- support fraudulent listing and/or utilisation
- result in unfair listing arrangements (e.g. applying for incorrect grouping)
- drive increases to patient out-of-pocket expenses

² The Department of Health and Aged Care is the regulator of listed devices on the PL through several mechanisms, including but not limited to the Therapeutic Goods Administration (TGA) and the Delegate of the PL and the PL Reform program.

- demonstrate repeated or wilful non-compliance (e.g. providing false and misleading information during application)
- retain medical device listings on the PL for products that are no longer active on the Australian Register of Therapeutic Goods (ARTG)
- provide false or misleading advertising of claims to receive rebate.

The Strategy and supporting activities focus on providing guidance and information that is relevant, clear, concise and easily accessible to help regulated PL stakeholders understand their obligations and responsibilities – and to encourage voluntary compliance.

How to comply with your obligations

Meeting compliance requirements is the responsibility of PL stakeholders. Most non-compliance is inadvertent, and the Department will work with stakeholders to resolve any issues, initially on an informal basis. You can help the Department by:

- **Understanding your responsibilities** – we will provide a range of educational resources to help you meet your legal obligations by targeting our compliance activities to the type of non-compliance identified.
- **Being proactive** – let us know as soon as you discover that you have made an incorrect listing or application.
- **Notify us** – it is important that you tell us if you have any concerns about behaviour that could constitute inappropriate listing and demonstrable non-compliance including fraud. Any information you can give assists us to take action to ensure the integrity of PL settings. *You can remain anonymous.*

PL stakeholders will be expected to be informed by and comply with the Legislation, Rules and Guide supporting the PL. Periodic reviews and amendments of the legislative instruments are undertaken to ensure the continued relevance and effectiveness of the PL program.

Further the Department will engage with medical technology and industry peak bodies, medical colleges and private health insurance industry peak bodies to support better PL compliance outcomes through program design, policy development and PL system improvements.

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Compliance Approach

The Department will monitor the behaviours of PL stakeholders and the operations of the PL for compliance against the established listing requirements.³ This is to ensure that the regulated benefit prices and the use of the devices continue to meet the regulatory requirements and controls throughout the period the product is listed on the PL.

These monitoring activities include post listing review processes, which may lead to device utilisation reviews and post market reviews. Post listing processes include:

- Assessing and investigating reports of problems/concerns with the utilisation of medical devices listed on the PL. *For example, significant increases in volumes and expenditure, concerning utilisation patterns of devices.*
- Checking evidence that medical devices continue to meet the requirements established at the point of listing – *including a focus on comparative clinical effectiveness and cost effectiveness, out-of-pocket expenses, approved usage, eligibility (scope and definition).*
- Undertaking periodic reference pricing activities to maintain alignment between public and private prices that underpins the PL benefit price.

The Department will ensure resources and effort are prioritised based on the seriousness and scale of compliance concerns. This allows for a responsive and proportionate approach to compliance utilising the wide range of tools and powers available to the Department.

A range of compliance and enforcement tools will be employed to address alleged non-compliance, either individually or in combination, and to encourage compliance with the regulatory and legislative requirements.

Tiers of non-compliance

The degree of non-compliance will be assessed according to the risk posed to the intended outcomes of the PL and its program, with compliance attention given to key risk factors informed by the compliance principles:

- **The nature of the contravention** – in particular, whether the non-compliance is limited to an administrative contravention as opposed to a contravention that indicates risk to patient safety
- **The volume of contraventions**
- Whether the PL stakeholder has **demonstrated previous non-compliances**
- Indicators of **deliberateness of the contravention**
- Whether the PL stakeholder indicates and demonstrates **a willingness to return to compliance**. This is particularly relevant in distinguishing between the more serious tiers of non-compliance (i.e. whether the PL stakeholder is taking a high adversarial approach or blatantly disregarding the need to return to compliance).

The tiers of non-compliance are not purported to be complete, thus there is inherently an exercise of professional judgement in assessing the tier of non-compliance.

Table 1 outlines the tiers of non-compliance, as shown overleaf.

³ Listing requirements are outlined in the [Private Health Insurance \(Prostheses\) Rules](#) and the [PL Guide](#).

Table 1: Tiers of non-compliance against the PL

Tier of non-compliance	Indicators
Voluntary compliance	<ul style="list-style-type: none"> • PL stakeholder is compliant with the PL Rules and Guide • Likely due to good understanding of PL Rules and Guide, good procedures to support compliance; and / or previous compliance review or enforcement response.
Minimal non-compliance	<ul style="list-style-type: none"> • Non-compliance is administrative in nature • Non-compliance identified is low volume • PL stakeholder has not had previous issues with compliance
Minor non-compliance	<ul style="list-style-type: none"> • Non-compliance is administrative in nature or does not indicate improper delivery of service • Non-compliance identified is low in volume • PL stakeholder has not had previous issues with compliance
Medium non-compliance	<ul style="list-style-type: none"> • Non-compliance is not merely administrative in nature, and may indicate improper delivery of service • Non-compliance identified is low to medium in volume • Evidence suggests the non-compliance may be deliberate or intended • PL stakeholder may have had previous issues with compliance
High non-compliance	<ul style="list-style-type: none"> • Non-compliance is not merely administrative in nature, and likely indicates improper delivery of service • Non-compliance identified is medium to high in volume • Evidence suggests the non-compliance may be deliberate or intended • PL stakeholder has had previous issues with compliance
Extreme non-compliance	<ul style="list-style-type: none"> • Non-compliance indicates improper delivery of service • Non-compliance identified is high in volume • Evidence suggests the non-compliance is likely to be deliberate or intended • PL stakeholder has had previous issues with compliance • PL stakeholder has not demonstrated motivation to return to compliance

Responsive enforcement model

A responsive enforcement approach will be used, which describes a principles-based way in which the Department (as the rule-enforcer) uses a hierarchy of enforcement interventions to respond to non-compliances in a proportionate manner – having considered the degree of non-compliance and the broader compliance behaviours of the industry.

Key principles underpinning the responsive enforcement approach include: using a hierarchy of interventions to influence PL stakeholder behaviour; and proportionality between identified non-compliance and the enforcement response.

This responsive enforcement approach would be consistent with current compliance enforcement better practices, with a focus on increasing education about the PL program and the existence of the compliance monitoring and audit function to support achievement of the compliance objectives.

Use of a responsive enforcement approach is accepted as better practice in most compliance and enforcement settings, as it has the benefits of:

- enabling compliance enforcement versatility
- being able to reach further with fewer resources
- targeting resources and more complex enforcement activity to more serious tiers of non-compliance
- incorporating both deterrent and more cooperative approaches to encourage compliance in a ‘socially intelligent’ way.

Against each of the tiers of non-compliance, particular enforcement activities will demonstrate a more proportionate and appropriate response. With reference to the enforcement responses available to the Department, the following table provides a **PL compliance enforcement model**.

Table 2: PL compliance enforcement model

Tier of non-compliance	Type of PL compliance enforcement activity							
Voluntary compliance								
Minimal non-compliance	Education and guidance							
Minor non-compliance		Caution / warning						
Medium non-compliance			Require corrective action	Enhanced or focused monitoring	Referral to TGA, APRA &/or ACCC			
High non-compliance					Delist	Civil proceeding		
Extreme non-compliance						Criminal prosecution		

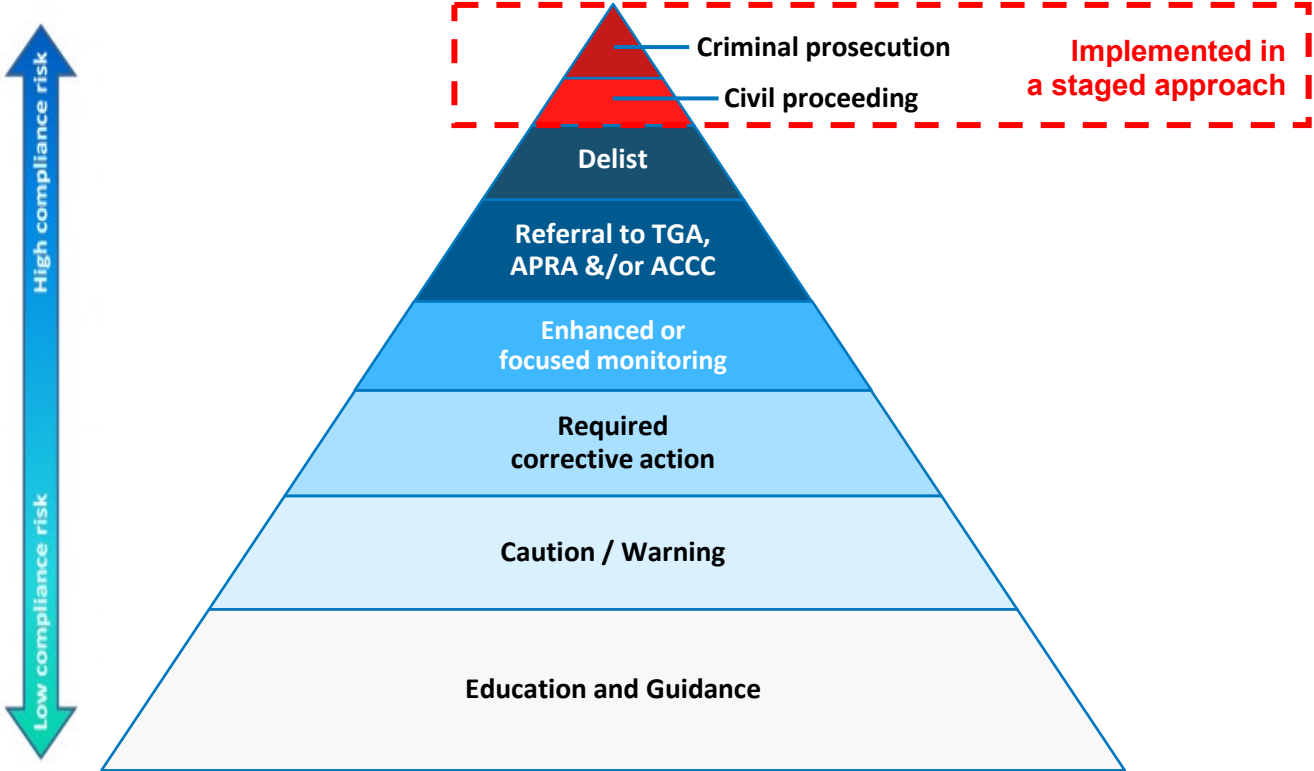
Implemented in a staged approach

The PL compliance enforcement model demonstrates versatility and incorporates both deterrent and more cooperative approaches to support and encourage compliance.

The above enforcement model results in the following **PL compliance enforcement pyramid** (Figure 1, overleaf). The rungs represent not only the potential escalation between different enforcement mechanisms (starting at the base, and moving up to the apex), but also the expected proportion of use of the response mechanisms – with most activities at the wide base and becoming less used as we move up the narrow rungs of the apex.

The preference is to start and have majority of actions at the bottom of the pyramid. This starting point is presumptive and will be overridden if the risk or conduct being responded to is disproportionately egregious, or in the case the lower strategies fail. In these cases, responses further up the pyramid will be preferred.

Figure 1: PL compliance enforcement pyramid



Identifying Non-Compliance

Information about potential non-compliance is received from a range of sources including tip-offs or complaints, data analysis and referrals from other stakeholders and agencies.

Tip off and complaints

When a complaint is received, it is reviewed and investigated as necessary. Any recommendations are notified to the relevant parties. Depending on the outcome of the investigation there may be recommendations for corrective actions and compliance activities.

Data Analysis

Data analysis will be used to identify anomalous or suboptimal utilisation patterns that may indicate compliance risks and non-compliant behaviour, providing a more proactive and independently driven approach to identifying compliance risks. Targeted data analysis and intelligence collection are used to investigate compliance concerns and issues.

Data analysis will be conducted by the PL Compliance team in the first instance (using in house capability and/or outside support). The results of these detection techniques are further validated through analysis that includes review by Prostheses List experts as well as engagement with relevant stakeholders to help understand the nature of the concerns and to identify the contributing factors.

Referrals to and from other Agencies

From time to time, medical devices may be suspended or cancelled from the ARTG. This may be voluntary or due to regulatory action from TGA, for a range of reasons including manufacturer recalls, reported safety issues, counterfeit medical devices and reported adverse clinical events. The PL Delegate may seek input from the TGA on the extent of the issues and reasons for their action.

It is the sponsor's responsibility to advise the PL Administration Section (PLAS) and complete the administrative requirements around removal from the PL as soon as a device is no longer included on the ARTG.

Where the Department identifies behaviour⁴ by a party for a device listed on the PL that suggests there are anti-competitive practices and behaviours related to the use and application of the PL, it may make a referral to the relevant regulators, such as Australian Prudential Regulation Authority (APRA) and the Australian Competition and Consumer Commission (ACCC).

Compliance Activities

The Prostheses List program, like other agencies, has a broad range of options to promote compliance. These can span from provision of education and guidance to facilitate compliance (including in instances of identified non-compliance) through to various legal avenues including civil and criminal responses to identified non-compliance. This spectrum equally applies to the enforcement of compliance with the Prostheses List and its program.

Compliance actions are strategies put in place to ensure PL stakeholders address identified non-compliance with the listing requirements.

The Department recognises that non-compliance can be inadvertent and works with PL stakeholders to resolve issues and promote good compliance practices. Compliance activities are targeted to the type of non-compliance identified. This allows for a responsive, proportionate and a risk-based approach to addressing compliance concerns.

The types of compliance actions required will depend on the nature of the non-compliance, its severity and frequency, and the PL stakeholder's willingness to comply and to address the issues. Where a PL stakeholder is willing to comply and needs minimal support, the level of compliance monitoring or compliance action needed is LOW. However, where there is an unwillingness to comply and/or a PL stakeholder needs significant support to comply, the level of compliance monitoring and action will be HIGH.

Corrective actions

The first step after identifying non-compliance is, in most instances, to give the PL stakeholder an opportunity to respond and outline how they propose to address the non-compliance. The PL stakeholder will be contacted in writing and/or by phone to discuss the issues and options to address the non-compliance. In this instance the PL stakeholder is encouraged to reflect on how they are complying with the rules and requirements for the PL and make changes if required. They

⁴ Behaviour includes communications (verbal or written), marketing and commercial practices that are misleading (real or perceived) from the intent of the PL.

may also be requested to review records and voluntarily review and re-assess any non-compliant activity that they identify.

If the PL stakeholder demonstrates an understanding of the problem and a willingness to act, this approach can deliver positive results and no further compliance action may be required.

The Department will undertake assurance, investigations, and (desktop) audit activities. The process is usually commenced with a request for information from the PL stakeholder (usually the sponsor) to assist in determining whether the rules and requirements for that listing are met. Where it is identified that there is a breach of the regulatory requirements, the Department will seek corrective action. If the PL stakeholder does not respond accordingly the Department may take further action such as delisting the product from the PL.

While the focus is to work with PL stakeholders to reduce the need for serious compliance action, in some circumstances compliance objectives cannot be met through education or by assisting stakeholders to comply. In these instances, the PL stakeholder:

- has a history, or there is evidence of, systemic non-compliance
- is acting in a fraudulent way
- has failed to provide complete, true and accurate information and/or documents
- has failed to respond to attempts to address compliance issue
- is unable to address their non-compliance.

In these circumstances the action taken will be proportionate to the behaviours exhibited and be aligned with any contractual responsibilities or legislative requirements. In high and extreme behaviours of non-compliance, civil proceedings and prosecution may be undertaken.

Legislative instruments

Participating PL stakeholders should make themselves informed of legal instruments⁵ relevant to the PL, including but not limited to:

1. **TGA legislation:** The *Therapeutic Goods Act*⁶, Medical Device Regulations and other instruments set out the requirements for conformity assessment, inclusion of medical devices in the Australian Register of Therapeutic Goods (ARTG), and compliance with the essential principles. It also addresses advertising, labelling, and product appearance.
 - Part 5-1 of the Act provides the regulatory framework in relation to advertisements about therapeutic goods in the public domain. The *Therapeutic Goods Advertising Code*⁷ prescribes the minimum requirements for the lawful advertising of therapeutic goods to Australian consumers. It ensures the marketing and advertising of therapeutic goods (including devices) is conducted in a way that promotes the quality use of the product, is socially responsible and does not mislead or deceive the consumer.

⁵ Copies of the legislation can be obtained from the Commonwealth of Australia Law website, available from < <http://www.comlaw.gov.au> >.

⁶ The *Therapeutic Goods Act 1989* sets out the legal requirements for the import, export, manufacture and supply of therapeutic goods (including devices) in Australia.

⁷ The 2021 Code has been prepared with an overarching objective of greater ease of reading for easier application of the advertising rules, while still meeting the requirements for a legal instrument prepared under the *Therapeutic Goods Act 1989*.

2. **Consumer law:** The Australian Consumer Law (ACL) in Schedule 2 of the *Competition and Consumer Act 2010* (Cth) is likely to apply. Specifically, section 18(1) of the ACL provides that a “person must not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive.” As providing information in connection with the listed device on the PL, any misleading or deceptive conduct in relation to trade or commerce will invoke the application of the ACL. Potential non-compliances or in breach of the Australian Consumer Law (ACL) in *Section 18 of the Competition and Consumer Act 2010* may be referred on to the Australian Competition and Consumer Commission (ACCC).
3. The ACL confers the ability for the Department to seek remedies for loss or damage arising from a PL stakeholders deceptive or misleading conduct.
 - Section 232 of the ACL states that a court may grant an injunction (restraint).
 - Section 236 of the ACL states that a person may make a claim to recover the amount of loss or damage suffered. There is a 6 year limit on such a claim.
 - Sections 237 and 242 of the ACL states that the court may make such orders as it deems appropriate.
4. The *Criminal Code Act 1995* (Cth) (the Criminal Code) may apply to prosecute a PL stakeholder that has provided misleading or false information to the Department under *s 137.1 of the Criminal Code*.
 - Under s 137.1, a PL stakeholder commits an offence if they give false or misleading information (or omits any matter or thing without which the information is misleading) to a Commonwealth entity (being the Department).
 - Under s 137.1(2), the PL stakeholder has the evidential burden of proving that the information is not false or misleading in a material particular.

Our Responsibilities

Principles underpinning the compliance activities

Principles underpinning the approach to guide compliance activities in relation to Prosthesis List are:

- **Risk based decision making** – Risks are actively identified, evaluated and monitored. Risks are assessed on their likelihood and potential consequences. Compliance activities are implemented to control risks.
- **Adopt a proportionate approach to non-compliance** – In the event that non-compliance is identified, the information available will be assessed and a reasonable response will be implemented based on the severity of the issues identified and the PL stakeholder’s willingness to comply.
- **Impartiality/fairness** – Focus on being impartial and objective, ensuring that if any non-compliance is identified, an opportunity to respond will be provided.
- **Act consistently** – Ensure a consistent approach, including how procedures and actions are applied.
- **Transparency** – Communicating with PL stakeholders to provide a clear understanding of the approach to compliance.
- **Accountability** – Compliance activities are consistent with the service delivery obligations of the contract including all referenced standards and guidelines. Decisions are appropriately and accurately documented and escalated/referred as necessary.

- **Respond in a timely manner** – All compliance cases and compliance activities will be undertaken in a timely way, noting that timing is dependent on the type of investigation, the complexity of issues identified and responses.

Conduct and Values

The Department upholds and complies with the APS Code of Conduct and APS Values that are set out in the *Public Service Act 1999*. No matter why you are contacted by our compliance staff, you can and should always expect:

- to be treated with respect
- to be given quality information
- fair and transparent service
- genuine consultation
- efficiency in the conduct of our processes.

Procedural Fairness

Should the matter escalate to a point of an administrative law decision, the Department will ensure procedural fairness by:

- avoiding actual and perceived conflicts of interest and act in an impartial and objective manner
- affording a person or organisation a reasonable opportunity to be heard and/or respond to the case before making an adverse decision affecting their interests.

This supports decisions that are fair, reasonable and made without bias.

Privacy

Your personal information will be handled in a way that protects your privacy in line with the *Privacy Act 1988 (Cth)* (Privacy Act). This includes the *Australian Privacy Principles* (APPs) and the *Australian Government Agencies Privacy Code*. The [Department's Privacy Policy](#) can be found on our website.

In addition, the *Private Health Insurance Act 2007* contain a range of secrecy provisions that further protect your sensitive information when undertaking our compliance and enforcement role.

The proposed data and information sharing provisions will enable a stronger evidence base for decisions associated with PL assessment, listing activities, post-listing reviews, compliance activities and continuous improvement activities.

The Department will continue to adhere to ensuring strong security and privacy protections regarding data and information sharing arrangements.

How to Report Non-Compliance

The Department is committed to preventing the occurrence of fraud and other inappropriate practices that pose risks to the PL settings. Specific concerns relating to a sponsor or a PL device are received through the email: prosthesescompliance@health.gov.au

Resources

Other relevant resources include:

- [The Protheses List](#)
- [Regulation and compliance](#)
- [The Protheses List reforms](#)
- [Protheses List Guide](#)
- [Private Health Insurance Act 2007](#)
- [Private Health Insurance Rules](#)
- [Private health insurance](#)

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All information in this publication is correct as of **August 2022**.