



Australian Government

Department of Health

The Red Book

Guidance on Laws Relating to Pathology and Diagnostic Imaging - Prohibited Practices

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Glossary

Term	Definition
beneficiary	a person who asks for or accepts a benefit from a person who is, or is connected to, a requester or provider
compliance	your obligations under the relevant legislation
market value	the market value of property, goods or services is the amount that a willing purchaser would have had to pay, at the time mentioned in sub regulation (2), to a vendor who was willing, but not anxious, to sell.
outlier Rent	Rental values which are considerably higher than comparable rents/properties
permitted benefits	<p>A benefit asked for or accepted by, or offered or provided to, a person (the beneficiary) who is, or is connected to, a requestor is a permitted benefit if:</p> <ul style="list-style-type: none"> a. both of the following apply: <ul style="list-style-type: none"> i. it is covered by subsection (2), (3), (4), (5) or (6) ii. it is not covered by subsection (7) b. It is covered by a determination by the Minister under section 23DZZIG
prohibited practice	commercial practices that breach the Prohibited Practices Provisions of the <i>Health Insurance Act 1973</i>
provider	persons who provide pathology or diagnostic imaging services
requester	persons who are entitled to request pathology or diagnostic imaging services
substantially different from the market value	more or less than 20 per cent variance from the market value

Strengthening Compliance

On 1 March 2008, changes to the laws prohibiting inappropriate commercial relationships between requesters and providers of pathology and diagnostic imaging services were introduced. The regulations to support these laws are referred to as the 'Prohibited Practice Provisions'. Part IIBA of the [Health Insurance Act 1973](#) (the Act), supported by regulations and legislative instruments, contain laws aimed at preventing inducements to request pathology and diagnostic imaging services. These provisions carry civil and criminal penalties of up to five years imprisonment for anyone breaking these laws.

As part of the [2017 Budget](#) the Australian Government announced its commitment to strengthening compliance under the Prohibited Practices Provisions as they relate to Pathology Approved Collection Centres (PACCs).

The implementation of the new compliance arrangements would include:

- the development of data analytics tools to identify irregularities in rent or referral rates or to identify other indicators of potential Prohibited Practices
- undertaking targeted compliance activities, including exercising powers to garner additional information relating to potential Prohibited Practices
- automating and streamlining existing approval processes for ACC arrangements, and
- extending ACC approvals from one to two years.

The Department has established a contact line where concerns relating to suspected breaches of the Prohibited Practices Provisions can be reported by:

- emailing provider.benefits.integrity@health.gov.au
- calling the Provider Benefits Integrity Hotline 1800 314 808.

This guide aims to clarify how these laws affect both requesters and providers of pathology and diagnostic imaging services.

Caution

This guide is not a substitute for legal advice. You should seek independent legal advice if you have any doubts about the legality of a proposed commercial arrangement. In addition to the provisions relating to prohibited benefits, the payment of inducements and similar arrangements may also be illegal under State and Territory laws relating to medical practice. Such arrangements may also raise concerns under the restrictive trade practices provisions of the [Competition and Consumer Act 2010](#) (Cth). Further information on anti-competitive behaviour can be found [on ACCC's website](#).



Why are these laws important?

Part of a healthcare practitioner's responsibility to his or her patient is to recommend other healthcare providers, including pathology and diagnostic imaging providers, based on the patient's clinical needs and best interests. Allowing this recommendation to be influenced by commercial arrangements between the practitioner and the provider may be illegal and/or unethical. It can also compromise patient outcomes and lead to over servicing.

The majority of healthcare practitioners do the right thing. For the minority who do not do the right thing, this conduct can have serious consequences. This includes a substantial fine (under a civil penalty provision, Individuals \$126,000 and Corporations \$1.26 million - amounts as at 1 July 2017) or, in some cases, imprisonment for up to five years (under a criminal offence provision). Breaches can also be referred to the Medicare Participation Review Committee, which has the power to exclude practitioners and companies from the Medicare system.

Both individuals and companies can be liable for breaches of the Prohibited Practices Provisions. Where a company is liable, executive officers who knew about the breach, and failed to take reasonable steps to prevent it, can also be personally liable.

Compliance and Enforcement

The Department is responsible for enforcing the Prohibited Practices Provisions. The Department's approach to compliance comprises a mix of education, support, deterrence and enforcement.

The Department recognises that it can take time to understand the laws and obligations in order to implement the necessary changes.

That is why the Department's compliance activities aim to encourage ongoing voluntary compliance with these laws by helping individuals understand their obligations and making it as easy as possible to comply.

Where there is a risk of non-compliance the Department will look at appropriate interventions, such as targeted information or a visit from a compliance officer to provide further assistance.

The Department's Compliance and Enforcement Strategy ([Appendix A](#)) outlines:

- the steps we will take to ensure that rents comply with the Prohibited Practices Provisions
- the key principles that underpin our approach to enforcement of the Prohibited Practices Provisions
- the regulatory tools at our disposal
- the outcomes that may be reached as a consequence of taking enforcement action.

The implementation timeline outlines the activities to be undertaken to implement the Compliance and Enforcement Strategy ([Appendix B](#)).

The Compliance and enforcement examples ([Appendix C](#)) demonstrate the compliance activities the Department may undertake to enforce the Prohibited Practices Provisions as they relate to ACCs. They are not intended to be exhaustive or to constrain the Department in undertaking compliance and enforcement activities.

It is important to note that deliberate or intentional abuse of the MBS and PBS will result in strict enforcement action under the Prohibited Practices Provisions.

What is prohibited?

The Prohibited Practice Provisions apply to benefits as depicted below:



Benefits can include cash, property, goods and services. A benefit passing, or potentially passing, between a requester/connected person and a provider/connected person, may be prohibited under a civil penalty provision ([see page 9 for a discussion of the criminal offence provisions](#)) if the benefit is **either**:

- reasonably likely to induce a requester (any requester, not just the particular individual involved) to request pathology or diagnostic imaging services from a provider; **or**
- related to the business of rendering pathology services or diagnostic imaging services.

Who is affected?

It is very important to understand that the Prohibited Practices Provisions affect anyone who can request or provide a Medicare-eligible pathology or diagnostic imaging service. Requesters include general practitioners, medical specialists, dental practitioners, podiatrists, physiotherapists, osteopaths, chiropractors and nurse practitioners.

In some circumstances the Prohibited Practices Provisions also apply to arrangements involving people who are “connected” to a requester or provider, such as:

- a relative of the requester or provider
- a company of which the requester or provider is a director, secretary or senior officer
- a company which is a related company of a corporate requester or provider
- a beneficiary under a trust where the requester or provider is the trustee
- the trustee of a trust where the requester or provider is a beneficiary
- a business partner of the requester or provider, or of a relative of a requester or provider
- a person whose relative is in a business partnership with a requester or provider
- a person or company who employs or engages the requester or provider
- an employee of or contractor to the requester or provider.

For medical practitioners who practise at a medical centre, the medical centre operator is connected to each such practitioner. This is the case regardless of the business structure of the particular medical centre.

Caution

“Permitted benefits” are permitted for the purposes of these laws only.



The fact that an arrangement is treated as “permitted” under these laws does not necessarily mean the arrangement complies with other laws or ethical standards applicable to the healthcare profession(s).

The laws do not interfere with normal business

The Minister for Health has approved a list of normal business practices that are unlikely to influence pathology or diagnostic imaging requests. An item that is listed in one of the boxes below is a “permitted benefit” and does not breach the laws, provided that:

- the listed “benefit” is not related to the number, kind or value of pathology or diagnostic imaging requests made by a requester to a particular provider; and
- taken with benefits of the same kind, it does not exceed the number that would usually be needed by the beneficiary (who is, or is connected to, a requester).

This list of items will be updated from time to time – you can check the current [Health Insurance \(Permitted benefits – pathology services\) Determination 2018](#) and the [Health Insurance \(Permitted benefits – diagnostic imaging services\) Determination 2008](#).

Some commercial arrangements are permitted under strict rules

The laws permit a limited range of benefits to be exchanged between requesters/connected persons and providers/ connected persons, **but only** if the benefit:

- is not related to the number, kind or value of requests for pathology or diagnostic imaging services made by the requester; **and**
- does not consist of the provision of staff or equipment at the premises of the beneficiary – whether full time, part time, or on a visiting basis - for the purpose of providing pathology or diagnostic imaging services; **and**
- is listed below; **and**
- satisfies all of the relevant requirements set out below.

The following list of “permitted benefits” sets out examples of arrangements that take place between requesters and providers. However, these arrangements may also take place between persons “connected to” requesters and providers and as outlined later in this guide, requesters and providers can be held liable as a result of the actions of such persons.

1. Leases or sub-leases to providers

Example:

A provider may pay rent to a requester (or someone other than the requester) if:

- the rent is not substantially different from the market value of the rent for the premises; and
- the rent is not related to the number, kind or value of requests for pathology or diagnostic imaging services made by the relevant requester; and
- if the provider is a pathology provider, the provider either establishes an approved collection centre or an accredited pathology laboratory in the premises within 60 days of entering the arrangement, or renders professional services in the premises, and does not use or occupy the premises for any other purpose.

These rules apply to any payment for the use or occupation of premises, including rent or a licence fee. However, these rules **do not apply** in the situation where the requester and provider are sharing the lease of premises – see the arrangement described at 6 in this regard.

'Market value' does not have a special meaning under these laws, but instead has its ordinary common law meaning:

- The definition of Market Value is set out in Regulation 20CB of the [Health Insurance Regulations](#) and relates to all property, goods or services.
- In a leasing context, this means the rent that a willing tenant would (at the relevant time) have had to have paid a willing, but not anxious, landlord to secure the lease (or sub-lease) over the premises.
- The market value of property, goods or services correspondingly means the price that a willing buyer would (at the relevant time) have had to have paid a willing, but not anxious, seller to acquire the property, goods or services.
- In determining market value, it may be that some value could be attributed to the convenience of the location.
- In essence, market value assumes an arms-length transaction with each party acting knowledgeably, prudently and without compulsion.

"Not substantially different" from the market value means not more than 20 per cent variance from the market value. As well as being within 20 per cent of the market value, the rent or other benefit must not be related to the number, kind or value of pathology or diagnostic imaging requests made by the relevant requester (Regulation 20CA of the [Health Insurance Regulations](#)).

If you have concerns about whether rent is within 20 per cent of market value, you may find it helpful to get an independent assessment of this. While the Act and the Regulations do not require requesters or providers to obtain a valuation to establish the market value of the rent for premises, or the market value of property, goods or services, obtaining an independent valuation from a qualified valuer can be helpful in ensuring that both parties understand whether a proposed arrangement complies with the prohibited practices provisions.

Caution

The rental is not permitted if it is linked to the number, kind or value of requests made by the requester even though it may not be substantially different from the market value.



If you are unsure if the rent is compliant, seek independent advice to assess the rental value.

2. Selling to providers

Example:

A provider may make a payment to a requester (or someone other than the requester) in exchange for property, goods or services if:

- the amount of the payment is not substantially different from the market value of the property, goods or services; and
- the amount of the payment is not related to the number, kind or value of requests for pathology or diagnostic imaging services made by the relevant requester.

3. Buying from providers

Example:

A provider may provide property, goods or services to a requester if:

- the consideration given by the requester in exchange for the property, goods or services is not substantially different from the market value of the property, goods or services; and
- the property, goods or services provided by the provider (for example, their volume or value) are not related to the number, kind or value of requests for pathology or diagnostic imaging services made by the relevant requester; and
- the property, goods or services do not consist of the provision of staff or equipment at the premises of the requester – whether full time, part time, or on a visiting basis - for the purpose of providing pathology or diagnostic imaging services.

“Not substantially different” from the market value means not more or less than 20 per cent variance from the market value.

4. Distribution of shareholdings and dividends

Example:

The profits or shares of a business that renders pathology or diagnostic imaging services may be distributed to a requester if:

- the amount of the benefit is in proportion to the requester’s interest in the business; and
- the amount of the benefit is not related to the number, kind or value of requests for pathology or diagnostic imaging services made by the relevant requester.

These rules apply to various dealings in shares including payment of dividends, rights issues and share buy-backs. For example, a requester who owns shares in a listed company which operates a pathology or diagnostic imaging business may receive dividends proportionate to his or her shareholding from time to time.

Caution

Requesters and persons connected to requesters should exercise caution (and, where uncertain, obtain independent legal advice) about any proposed arrangement involving a distribution of profits or shares where:



- they are offered the purchase of shares at a price which is substantially different to market value, or are offered dividends that are not proportional to their investment; or
- it is implied, proposed or expected that requesters who are, or are connected to, investors will switch their pathology or diagnostic imaging requests to a provider associated with the arrangement – for example where:
 - the business model for the arrangement will not be sustainable, or does not make commercial sense, if such switching does not occur
 - requesters are unlikely to choose the relevant provider on the basis of their patients' clinical needs and best interests
 - the returns are linked to the number, kind or value of requests.

Features such as these may indicate that the benefit is not proportional to financial interest, may be substantially different from market value of the purchase price of the shares, and/or is related to the number, kind or value of requests for pathology or diagnostic imaging services made by the requester.

It is also worth remembering that any:

- a. contract, arrangement, understanding or concerted practice;
- b. misuse of market power; or
- c. exclusive dealing;

will breach the [Competition and Consumer Act 2010](#) (Cth) if it has the purpose, effect or likely effect of substantially lessening competition. See the [Australian Competition and Consumer Commission website](#).

If there is any evidence of conduct that may raise concerns under the Competition and Consumer Act, that conduct may be referred to the Australian Competition and Consumer Commission for further consideration.

If you have any doubts about the legality of a proposed commercial arrangement, please seek legal advice.

5. Employment by providers

Example:

A provider may pay a requester remuneration as an employee or under a contract for services if:

- the remuneration is not substantially different to the usual remuneration paid to persons engaged in similar jobs / under similar contracts; and
- the remuneration is not related to the number, kind or value of requests for pathology or diagnostic imaging services made by the relevant requester.

As well as not being substantially different from the usual remuneration, the remuneration paid must not be related to the number, kind or value of pathology requests made by the relevant requester.

6. Payment for shared property, goods or services

Example:

A provider may make a payment for property, goods or services which are shared with a requester if:

- the payment is proportionate to the provider's share of the cost of the property, goods or services; **and**
- the payment is not related to the number, kind or value of requests for pathology or diagnostic imaging services made by the relevant requester; **and**
- if the provider is a pathology provider and the payment relates to shared use or occupation of premises, the provider either establishes an approved collection centre or an accredited pathology laboratory in the premises within 60 days of entering the arrangement, or renders professional services in the premises, and does not use or occupy the premises for any other purpose.

An example of such an arrangement is where a provider and a requester agree to split the cost of outgoings (e.g. power, telephone) for particular premises. If, say, the provider uses 10 per cent of the electricity and pays for 10 per cent of the electricity, the arrangement is permitted. If the provider uses 10 per cent of the electricity and pays for 100 per cent, the arrangement is prohibited.

Are valuations required?

While the Act and the Regulations do not require requesters or providers to obtain a valuation to establish the market value of the rent for premises, or the market value of property, goods or services, obtaining an independent valuation from a qualified valuer can be helpful in ensuring that both parties understand whether a proposed arrangement complies with the Prohibited Practices Provisions.

Criminal offence provisions

In addition to the civil penalty provisions (punishable by a fine) discussed above, the laws include criminal offence provisions (punishable by imprisonment). Broadly speaking these are offences:

- **for any person:** the person (whether or not a provider) offers or provides a benefit to a second person (whether or not a requester) intending that the benefit will induce a requester to request pathology or diagnostic imaging services from a particular provider
- **for requesters:** a requester or another person accepts a benefit where the intent behind the providing of the benefit is to induce the requester to request services from a particular provider and the requester knows this intent, or a requester or another person has asked for or accepted, a benefit and the requester intends that the benefit will result in his or her requests being directed to a particular provider; **or**
- **for providers:** a provider knows that another person has offered or provided a benefit to a second person (whether or not a requester) with the intention that the benefit will induce a requester to direct requests to the provider, **and** the benefit is not a “permitted benefit” within the meaning of the laws.

Threats

The laws also prohibit the making of threats in certain circumstances, including where:

- a provider threatens a requester or a person connected to a requester, and the threat is **either**:
 - reasonably likely to induce a requester (any requester, not the particular individual involved) to request pathology or diagnostic imaging services from a provider; **or**
 - related to the business of rendering pathology services or diagnostic imaging services; **or**
- **any** person threatens a second person intending that the threat will induce a requester to request pathology or diagnostic imaging services from a particular provider.

A provider who engages in the conduct set out in the first dot point could be found to have contravened a civil penalty provision. A person who engages in the conduct set out in the second dot point could be found to have committed a criminal offence.

An example of a prohibited threat would be a provider who rents space from a requester threatening to stop paying rent if the requester does not increase his or her pathology or diagnostic imaging requests to the provider.

A requester who threatens to switch his or her pathology or diagnostic imaging requests to another provider unless a benefit is given is likely to breach one of the other provisions – for example, asking for a payment with the intention that if the payment is made, the requester will direct requests to a particular provider.

Unauthorised conduct by intermediaries

To prevent easy evasion of the laws by channelling non-permitted benefits through third parties, under certain provisions requesters and providers may be held liable as a result of the actions of persons connected to them. This includes the actions of relatives, members of partnerships or those with some other close financial relationship.

Under other provisions, requesters and providers may be held liable as a result of the actions of “another person” who may or may not be connected to them.

There are provisions in the laws to protect requesters and providers from being held liable as a result of the actions of others. These protections apply if a requester or provider becomes aware of prohibited practice and [reports it to the Department within 30 days](#).

This ensures that no one can be held liable as a result of the actions of another person unless they were aware of, and failed to report, those actions.

Concerns which relate to the use or occupation of pathology approved collection premises can be raised with the Department by:

- emailing provider.benefits.integrity@health.gov.au
- calling the Provider Benefits Integrity Hotline on 1800 314 808.

Further information

Further information is available on the [Department's website](#) or by emailing Legislativeamendments@health.gov.au.

Permitted benefits for pathology

Under the laws:

- a pathology provider or connected person can offer or provide the following benefits to a beneficiary (who is, or is connected to, a requester); and
- a beneficiary can ask for, or accept, the following benefits from a pathology provider or connected person:
 - aids for requesting pathology or viewing results, if they can only be used for purposes connected with pathology e.g. requesting software
 - an arrangement under which the provider stations pathology staff (an approved pathology practitioner or his or her delegate) or equipment at the beneficiary's premises for the sole purpose of providing preliminary analysis or advice in relation to specimens collected during procedures performed at the premises by fine needle aspiration, bone marrow aspiration, trephine or frozen section examination
 - an arrangement under which the provider stations pathology staff at the beneficiary's premises, where those premises are a hospital, to collect pathology specimens from hospital inpatients
 - an arrangement under which the provider stations pathology equipment at the beneficiary's premises, where those premises are a hospital, for use in the rendering of services relating to pathology to hospital inpatients
 - educational material about pathology (including for patients)
 - appropriate educational sessions on pathology for the beneficiary, not including travel or accommodation costs, attendance at an entertainment or sporting event, or excessive hospitality
 - reasonable, infrequent gifts or hospitality linked to a significant occasion (and not to pathology requests) and not capable of conversion to cash e.g. flowers given because of the death of a family member of the requester, a bottle of wine at Christmas
 - pathology request forms, telephone results pads, stock request pads and promotional items with no resale value for the beneficiary and which are clearly identified as coming from the relevant pathology provider
 - a refrigerator used only for (and necessary for storage of) pathology specimens, specimen transport containers and specimen pick up receptacles, in each case which are labelled as the property of the provider
 - the following items used for the collection of pathology specimens for testing by an accredited pathology laboratory:

Needle barrel holders

Syringes (5 ml or larger)

Individual alcohol wipes

Small test tube rack

Cervix spatulas

Vacutainer or equivalent tubes for collection

21 or 23 gauge needles

Spreaders for blood files

Spray fixative

Cyto brush

Direct to vial kits	Slides and slide carriers or holders
Formalin or other fixative	Appropriate containers & media for specimens
Punch biopsy instruments	Microbiological or virology swabs & transport media
Urine containers	Faeces containers
Paediatric urine collection kits	Chlamydia specific collection & transport receptacles
Blood culture bottles	Petri dishes
Timed urine collection containers	Specimen biohazard bags & rubber bands
Faecal fat collection containers	Glucose drinks for a glucose tolerance test
Disposable vaginal speculums	Tuberculosis specific collection receptacles

Appropriate containers and media for urine, sputum & other body fluid cytology and cytology samples collected directly from tissues by cytology of fine needle aspiration

Centrifuges if they are labelled as the property of the provider and necessary to ensure that specimens are not damaged.

Permitted benefits for Diagnostic Imaging

Under the laws:

- a diagnostic imaging provider or connected person can offer or provide the following benefits to a beneficiary (who is, or is connected to, a requester); and
- a beneficiary can ask for, or accept, the following benefits from a diagnostic imaging provider or connected person:
 - aids for requesting diagnostic imaging or reading film or images, provided they can be used for requesting/reading diagnostic imaging from any provider and either:
 - a. can only be used for purposes connected with diagnostic imaging; or
 - b. have more than one use, but include special features that assist with requesting diagnostic imaging or reading film or images
 - an arrangement under which the provider stations staff or diagnostic imaging equipment at the beneficiary's premises if the premises are a hospital, or are more than 30 km by road from a radiology facility supervised by a radiologist, or the staff or equipment are stationed at the premises for the sole purpose of enabling diagnostic imaging to be rendered during a surgical procedure performed at the premises
 - free or discounted diagnostic imaging services provided to a requester, or a patient who is connected to a requester (e.g. a requester's spouse)
 - educational material about diagnostic imaging (including for patients)
 - appropriate educational sessions on diagnostic imaging for the beneficiary, not including travel or accommodation costs, attendance at an entertainment or sporting event, or excessive hospitality
 - reasonable, infrequent gifts or hospitality linked to a significant occasion (and not to diagnostic imaging requests) and not capable of conversion to cash e.g. flowers given because of the death of a family member of the requester, a bottle of wine at Christmas
 - diagnostic imaging request forms and promotional items with no resale value for the beneficiary and which are clearly identified as coming from the relevant diagnostic imaging provider.

Frequently asked questions

Q. A Medical practice has advertised space for lease in its building. The medical practice has indicated the opening hours of the pathology or diagnostic imaging rooms in the building must match the opening hours of the medical practice. Is this arrangement permitted?

A. The laws are not intended to prevent competition between providers on the basis of the benefits they provide for patients. The laws prohibit providers from offering certain benefits to requesters but they do not prohibit a provider from offering convenience to patients.

Q. I am a medical practitioner and a provider has offered to sell me a 10 per cent share in his practice. He has indicated that I will receive dividends in proportion to the shares that I hold in the practice. The shares are worth \$10 each but I have been told that I only have to pay \$1 for each share. The provider has assured me that I am under no obligation to refer my patients to the practice. Is this arrangement permitted?

A. This is not a permitted benefit. A requester may buy shares from a provider where the price paid to the provider is not substantially different to the market value of the shares. Here there is a 90 per cent discount to the market value – well above the 20 per cent permitted variation. Depending on the circumstances either civil or criminal penalties may apply.

As a general rule, caution should be exercised with any proposed arrangement which does not appear to make commercial sense if requests are not factored in.

Q. I am a health care practitioner other than a doctor (e.g. a podiatrist, physiotherapist or osteopath) and I refer patients to a radiologist for x-rays. Patients receive Medicare benefits for the x-rays that I request but the services that I provide are not funded under Medicare. Do the laws apply to business arrangements that I have with the radiologist?

A. The laws apply to anyone who can request a Medicare-funded pathology or diagnostic imaging service and those that are connected to them, regardless of whether they provide services funded under Medicare.

Q. I am a chiropractor and I have been approached by a diagnostic imaging provider to lease part of my building. He intends to operate an accredited Location Specific Practice Number (LSPN) at the premises. I have also been asked to work for the provider as a radiographer at the LSPN, under a contract for services, taking x-rays for patients that I refer to the practice. Am I permitted to lease part of my building to the provider and also work for the provider for the services that I request?

A. The rental aspects of this arrangement are permitted provided that the rent is not substantially different from market value and does not relate to the number, kind or value of your diagnostic imaging requests. For example, if the per square metre rent paid by the diagnostic imaging provider is no more or less than 20 per cent above the per square metre rent you pay for the whole building, and does not vary according to your requests, the rent is likely to be compliant.

The remuneration is also permitted provided it is not substantially different from the usual rate for a radiographer's time and does not relate to the number, kind or value of your diagnostic imaging requests.

The latter requirement means that you cannot be paid per x-ray examination, because this would mean that your remuneration will vary with the number of requests you make.

Q. I am a pathology provider and large medical practice refers all of its pathology testing to my laboratory. Although the pathology specimens are collected at the medical practice, I provide the items the practice needs to collect and store the specimens free of charge. Nurses working for me also provide nursing services for the medical practice. These services include collecting pathology specimens on behalf of the practitioners. I pay all the costs associated with the nurses because all of the specimens the nurses collect are sent to my laboratory. Is this arrangement permitted?

A. Generally speaking, pathology providers can supply the items necessary for the collection and storage of specimens free-of charge to requesters. This is because the Minister for Health has approved those items under the [Health Insurance \(Permitted benefits - pathology services\) Determination 2008 \(Cth\)](#) on the basis that they are unlikely to influence pathology or diagnostic imaging requests. You should check the detailed list of permitted items set out in the current version of that determination before proceeding. However, the nursing arrangements are prohibited. The permitted benefits a provider can give a requester specifically exclude stationing staff at the premises of a requester.

This scenario differs from collection staff stationed at an approved collection centre leased from a requester by a pathology provider. Collection staff working at an ACC are on the premises of the pathology provider (occupied by the provider under the lease) rather than premises of a requester.

Q. I am a provider renting a premises from a requester. My lease is due for renewal and the requester has asked me to pay significantly more than I am currently paying. Is a requester permitted to charge rent that is substantially different to the current rate?

A. The issue here is not whether the rent is substantially different from the current rate, but whether it is substantially different from the market value.

You should make some enquiries about market rental in the local area. If the rent proposed by the requester is more or less than 20 per cent of the market value, or relates to the number, kind or value of the requester's requests, the requester is breaching the prohibited practices provisions.

Q. I am a pathology service provider who operates an ACC from leased premises. My lease has to be varied to reflect changes in the level of outgoings I pay. Do I need to submit the new lease?

A. Yes. The new lease needs to be submitted.

Note: From 1 July 2018 new lease agreements and all applications are to be submitted through Health Professional Online Services (HPOS) with supporting documents attached electronically.

Q. Do I need to submit a new lease if there is a change to the premises or the lease arrangements?

A. Yes. The new lease needs to be submitted.

Note: From 1 July 2018 new lease agreements and all applications are to be submitted through Health Professional Online Services (HPOS) with supporting documents attached electronically.

Q. I am a provider and I have existing leases on several premises which I rent from requesters. It will take me some time to ensure that what I pay for those leases is compliant (i.e. that what I'm paying is not 20 per cent different to market value). How much time do I have to go through that process?

A. Anyone who is a party to a lease between a provider and a requester (or a connected person as defined in the Act) should closely review their arrangements to ensure compliance with the Prohibited Practices Provisions.

If you have leases under which the rent or other benefits paid may contravene the prohibited practices provisions, you should seek to regularise the rent or other benefits paid.

The Department's initial approach in relation to any anomalies in ACC rents and other benefits will be to support you (and requesters who may be a party to a lease or other commercial arrangements with you) to comply with the Prohibited Practices Provisions. Attempts by parties to resolve any issues would be considered in determining whether further action is needed to address potential non-compliance. Further detail on the Department's proposed approach to compliance and enforcement is set out at [Appendix A](#).

Q. I am a pathology service provider in the process of negotiating a new lease. Should I be checking now to make sure that the new lease is compliant with the Market Value Regulations?

A. Providers should ensure that rent or other benefits do not relate to the number, kind or value of requests and are within 20 per cent of market value. Providers should check this before the ACC registration form is submitted. Documented evidence of having checked local market rental values and/or having sought an independent valuation by a qualified valuer would be considered by the Department in any review of the rental arrangement.

Note: From 1 July 2018, all new leases and subleases must be submitted through HPOS with the Application of an Approved Collection Centre form (HW035) or Approved Collection Centres Renewal form (HW053). These forms are available on the [Human Services](#) website.

Q. Do requesters and providers need to obtain their own valuations?

A. The legislation does not require requesters or providers to obtain their own valuations. However, an independent valuation from a suitably qualified valuer can be helpful in establishing market value so that both parties are better placed to understand whether a proposed arrangement complies with these laws. However, that **as well as** being within 20 per cent of market value, the benefit must not be related to the number, kind or value of pathology requests made by the relevant requester.

Q. How do I report suspected breaches of the inappropriate practices provisions?

A. Concerns relating to suspected breaches of the Prohibited Practices Provisions (whether in relation to pathology services or diagnostic imaging services or in relation to rents or other benefits) may be reported to the Department by:

- emailing provider.benefits.integrity@health.gov.au
- calling the Provider Benefits Integrity Hotline on 1800 314 808

Appendix A - Compliance and Enforcement Strategy

The Department of Health is the Australian Government agency with primary responsibility for the administration of the [Health Insurance Act 1973](#) (Cth).

Our role requires us, among other things, to support the appropriate use of Medicare funding through enforcement of the Prohibited Practices Provisions set out at Part IIBA of that Act. We will, from February, undertake compliance and enforcement activities which are directed to ensuring that payments of rent or other benefits (**Rents**) under arrangements for use of premises as an Approved (Pathology) Collection Centre (ACC) do not contravene those provisions.

This strategy identifies:

- the steps we will take to ensure that Rents comply with the Prohibited Practices Provisions;
- the key principles that underpin our approach to enforcement of the Prohibited Practices Provisions;
- the regulatory tools at our disposal; and
- the outcomes that may be reached as a consequence of taking enforcement action.

1. Scope of this strategy

The compliance and enforcement activities we undertake will impact on a broad range of stakeholders. They include requesters of pathology services (**requesters**) such as general practitioners and providers of those services including approved pathology authorities (**APAs**) and approved pathology practitioners (**providers**). They may also impact on individuals and incorporated entities who, because of the structure of a requester's or provider's business, are *connected* for the purposes of the prohibited practices provisions with requesters or providers.

They may include:

- family members (whether in their own right, in their capacity as directors or officers of the requester or provider or a related company, as beneficiaries under a trust, or as members of a partnership);
- employees of, or contractors to, a requester or provider;
- directors or officers of the requester or provider or a related company;
- related companies (including service companies or trustee companies); and
- trustees or beneficiaries under a trust.

For simplicity, throughout this strategy we refer to those potentially impacted by our compliance and enforcement activities as the *affected sector*.

2. The Prohibited Practices Provisions

2.1 Our role and prohibited practices

The Prohibited Practices Provisions were inserted at Part IIBA of the [Health Insurance Act 1973](#) (Cth) (the Act) in 2007, following concerns about the potential for inducements for referrals between requesters and providers of pathology (and also diagnostic imaging) services.

The provisions prohibit a requesters or providers from asking for, accepting, offering or providing "prohibited benefits", that is, a benefit that:

- would be reasonably likely to induce a requester to request any of those kinds of services from a provider; or
- is a related to the business of rendering pathology services; and
- is not a "permitted benefit" under the Act.

Rent for premises leased or sub-leased by a provider from a requester and used for an ACC (for example, premises co-located with a healthcare facility) may, in some circumstances, be a "prohibited benefit" under the Act. Under the [Health Insurance Regulations 1975](#) (Cth), rent may be a prohibited benefit where it is "substantially different" from market value. That is, where the difference between the market value and the Rent is more than 20 per cent of the market value.

A contravention of the Prohibited Practices Provisions can expose a requester or provider to civil penalty proceedings, with the penalty for individuals \$126,000 and \$1.26 million in the case of a body corporate such as a company (amounts as at 1 July 2017). Asking for, accepting, offering or providing a prohibited benefit may also be a criminal offence, punishable by 5 years' imprisonment or, in the case of a company, a large pecuniary penalty. A successful proceeding or prosecution may also result in a range of other sanctions against the requester and/or provider involved in the contravention or offence. Some of these are identified at section 4.3 below.

3. Our approach

3.1 What we will do

We will focus on ACC rents which, on the basis of data, represent the greatest risk to the integrity of Medicare benefits claims. Initially, in the absence of a comprehensive dataset, we will focus on Rents which are, on the data available, outliers.

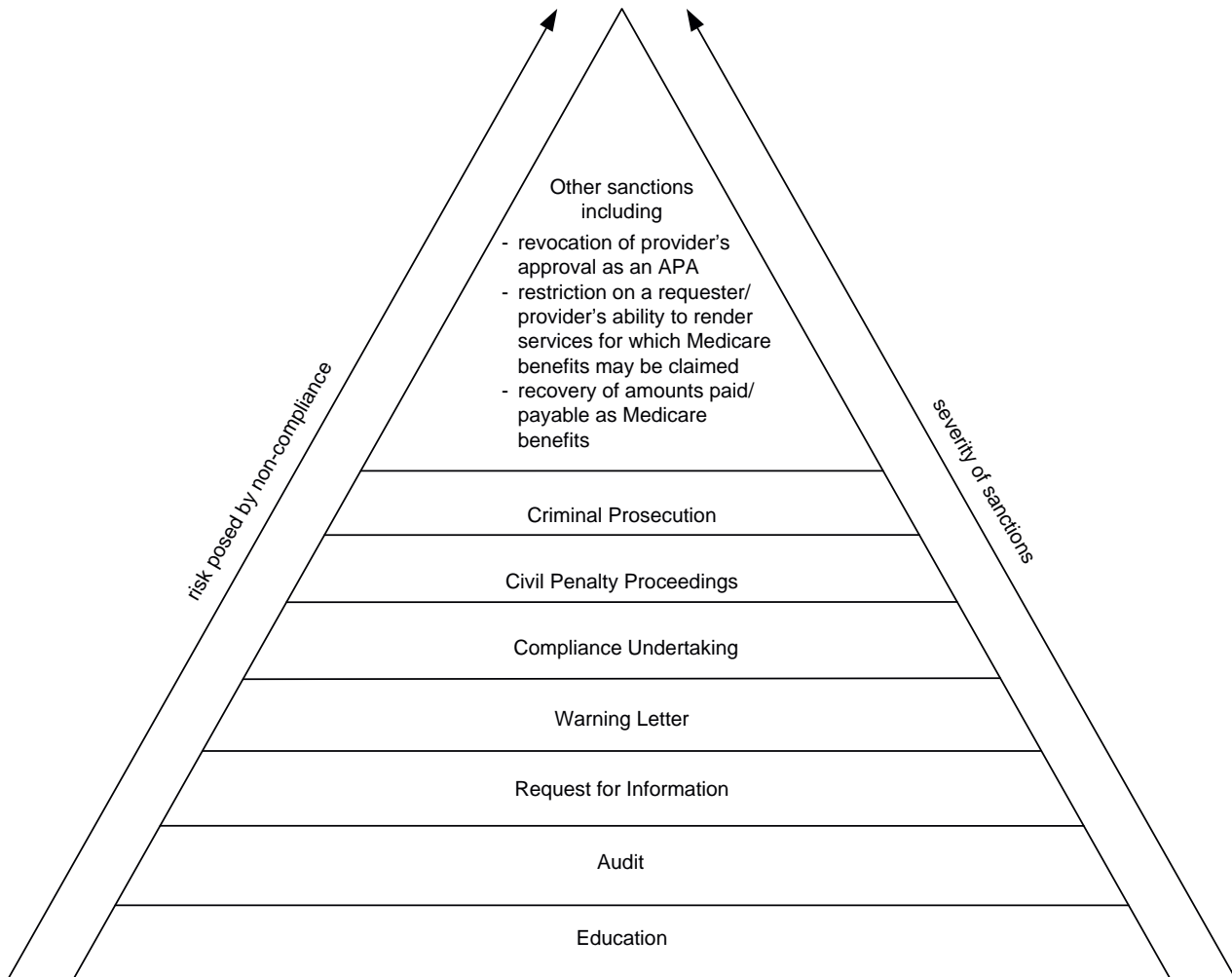
Most of our regulatory efforts will be directed towards encouraging voluntary compliance. We will generally do this by writing a letter requesting further information about Rent to those who are parties to arrangements under which outlier Rents are paid or payable. We will also educate the affected sector as to the market for ACC rents.

We will also conduct ongoing audits of lease and other arrangements of ACC premises. Our compliance efforts may be escalated and involve more coercive regulatory tools (including the commencement of civil penalty proceedings or criminal prosecution) where attempts to secure voluntary compliance are unsuccessful or where there is evidence of a deliberate intention to contravene the Prohibited Practices Provisions.

Without limiting our rights, we will take enforcement action where we have reasonable grounds to believe that parties:

- are unwilling to comply with; or
- may be engaged in repeated, deliberate or systematic contravention of the prohibited practices provisions.

This is likely to represent a much smaller proportion of our regulatory caseload. Our regulatory approach can be represented by the following enforcement pyramid, which draws on the work of Braithwaite¹:



Sections 4.1 and 4.2 provides more detailed information about the compliance and enforcement tools identified in this pyramid.

¹ Braithwaite, J. *Responsive Regulation: Transcending the deregulation debate* (1992) OUP: New York, p35

Guiding principles

Our approach is, and our compliance and enforcement activities will be:

(a) Proportionate

We recognise that there will be a spectrum of compliance behaviours and that requesters and providers and people connected to them have a range of motivations.

We acknowledge that the majority of Rents for Approved Collection Centres will be compliant and that the affected sector, as a whole, wants to comply.

Our compliance and enforcement activities will be directed at both requesters and providers (and those connected to them) so that the compliance burden does not fall disproportionately on one group.

Our regulatory responses will reflect the principle of minimal sufficiency: we will take the regulatory response that is minimally sufficient to secure compliance.

(b) Data-driven

We will develop a dataset to help us understand the state of the market for Approved Collection Centres Rents and use this to direct our activities.

The dataset may incorporate data sources including:

- publicly available information (e.g. demographic information available through the Australian Bureau of Statistics, information available from Australian Property Monitors);
- publicly available information about requesters or providers (for example, information on a requester's or provider's website or information supplied to a stock exchange);
- information obtained by us from telephone calls to or emails received by the Pathology Rents Section contact line;
- information supplied by an applicant APA in an application for an Approved Collection Centre; and
- other information available to us about the affected sector, including Medicare claims data.

(c) Risk-based

It will take time to collect market intelligence about the arrangements which represent the greatest risk to the integrity of Medicare and to develop a comprehensive dataset.

We recognise that our initial approach, which focusses on outlier Rents, may be under-inclusive or over-inclusive. For this reason, we intend (as discussed at section 5) to review this strategy periodically and, later, to undertake formal evaluation to assess its effectiveness in producing behaviour change.

We acknowledge that in many cases, there may be sound reasons - which may be premises-specific, geographic, demographic or otherwise - for outlier status. Requesting further information from parties whose Rent is an outlier will allow us to identify those cases and, if appropriate, discontinue compliance action.

(d) **Transparent**

We will be clear about our proposed approach to compliance and enforcement. We will ensure that our regulatory processes support consistent enforcement outcomes.

We will report to the affected sector on our compliance and enforcement activities with respect to Rents.

(e) **Collaborative**

Our approach has been informed by:

- our discussions with the affected sector (including peak bodies representing both requesters and providers);
- previous attempts at enforcing the Prohibited Practices Provisions; and
- contemporaneous amendments to the "Red Book".²

We have also considered the approaches of other conduct regulators, including those of the Australian Health Practitioner Regulation Agency and the Australian Competition and Consumer Commission.

We will continue to work closely with the affected sector and will provide it with information about the state of the market for Approved Collection Centre Rents. We will also provide the affected sector with opportunities for engagement with us and with ongoing educational support.

4. **Regulatory toolkit**

Our compliance and enforcement activities will rely on the following tools:

4.1 **Compliance tools**

Education and engagement, which are key to encouraging behaviour change and supporting a compliance mindset.

We may carry out one or more of the following activities to support compliance:

- work with requesters or providers to understand the considerations that may influence Rents asked for, accepted, offered or provided;
- develop specific educational tools to respond to identified areas of concern;
- engage with requesters and providers and other stakeholders through forums, meetings with peak bodies and other activities;
- advise requesters and providers when we take compliance or enforcement action to provide a further insight into our thinking;
- communicate information about the market for Approved Collection Centre Rents to the affected sector;
- write to parties to an agreement where it appears that the Rent payable or paid is an outlier based on the data and may risk non-compliance; and/or
- partner with peak bodies on projects designed to support or improve this strategy.

² *Changes to Laws Relating to Pathology and Diagnostic Imaging* (2008) Department of Health and Ageing: Canberra

4.2 Enforcement tools

Our regulatory toolkit also comprises a range of statutory powers exercisable by us in the circumstances set out in the Act and the Medicare Act and contractual rights arising under a provider's APA undertaking. It also includes a range of rights exercisable by the Commonwealth under the general law.

Our tools allow us, among other things, to:

- make a request, at any reasonable time and with 12 hours' notice, to inspect the premises, including for the purposes of inspecting documents and other records related to the rendering of services in the premises;
- make a written request to provide relevant information specified in the request relating to the premises or the services provided, including any matter arising out of a provider's APA undertaking and copy or disseminate that information;
- where we have reasonable grounds for believing that a person has contravened a civil penalty provision or committed an offence:
 - require a person to give us information or produce a document that is in the person's custody or control;
 - with consent of the occupier or under warrant, enter premises which we have reasonable grounds to believe are premises at which activities associated with the rendering of services for which Medicare benefits have been paid or may be payable, have been or are being carried out and:
 - search those premises;
 - take photographs;
 - take extracts from any book, document or record on the premises; and
 - look at computer data and if relevant, copy that data;
- without limiting its rights under law, obtain an undertaking in favour of the Commonwealth under which a provider and/or requester commits to performing certain steps to ensure its compliance with the prohibited practices provisions;
- make an application to the court for an order that a provider or requester pay the Commonwealth a pecuniary penalty. That is, bring civil penalty proceedings against a provider or requester; and/or
- make a referral to the Commonwealth Director of Public Prosecutions for criminal prosecution where we have reasonable grounds to believe that a provider or requester has committed a criminal offence.

We may use one or more of our regulatory tools to address non-compliance. Where we use more than one tool, we may do so concurrently or successively, depending on the circumstances and any statutory or other limitations.

4.3 **Enforcement outcomes**

The enforcement outcomes that may result from the exercise of our regulatory tools include:

- a court order against a requester or provider for payment of a civil penalty;
- where a requester or provider is found guilty of a criminal offence, imprisonment;
- where proceedings against or prosecution of a requester or provider are successful, but subject to the requirements of the Act:
 - revocation of a provider's approval as an APA and revocation of an employee practitioner's approval as an approved pathology practitioner; and/or
 - restrictions on a requester or provider's ability to claim Medicare benefits for services rendered; and/or
 - recovery of amounts paid or payable as Medicare benefits.

5. **Review and evaluation**

5.1 **Review**

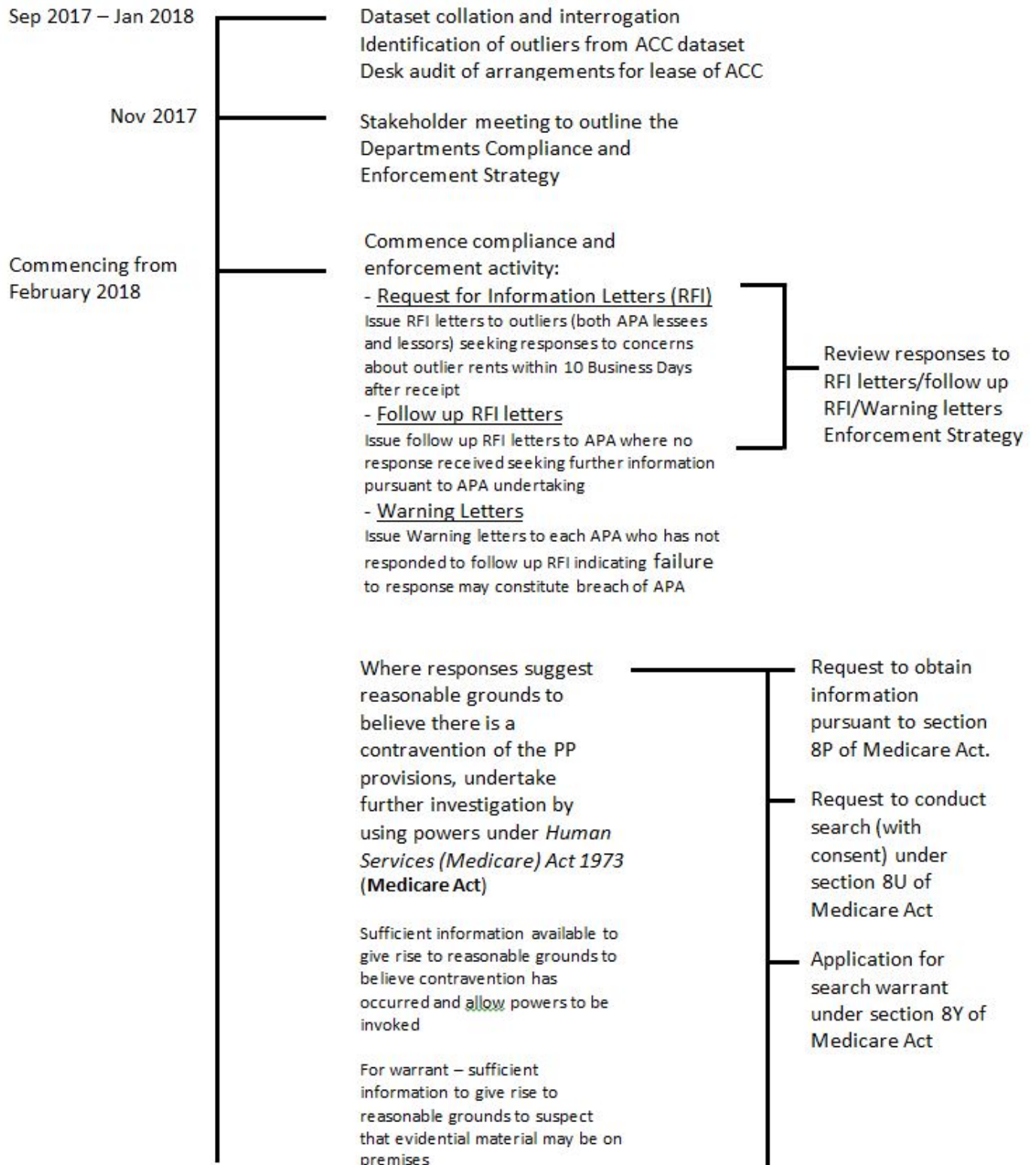
While this strategy describes our intended approach to compliance and enforcement, it may be necessary for us to periodically review this approach to determine whether what we are doing is improving Rent compliance, to incorporate any refinements and to accommodate any changes to regulatory practice across government.

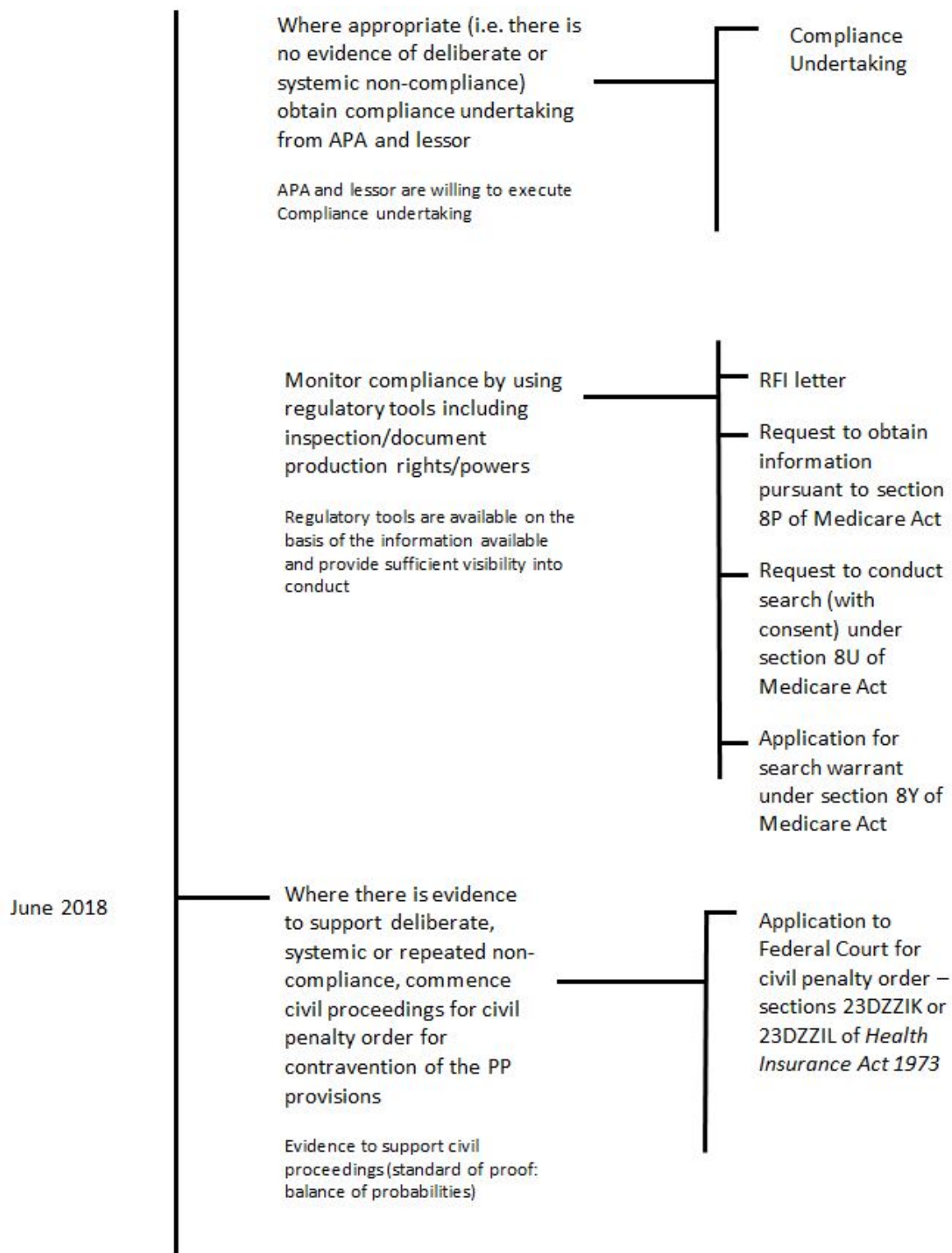
We will communicate any substantive changes to our proposed approach to the affected sector.

5.2 **Evaluation**

This strategy will be subject to formal evaluation in 2019. The evaluation process will involve and incorporate feedback from the affected sector. We will communicate key conclusions of the evaluation publicly.

Appendix B – Compliance and Enforcement timeline





Appendix C – Compliance and Enforcement examples

The following examples demonstrate the compliance activities the Department may undertake to enforce the prohibited practices provisions as they relate to ACCs. They are not intended to be exhaustive nor to constrain the Department in undertaking compliance and enforcement activities.

Example 1

A pathology provider has an ACC in a general practice. It leases the space occupied by the ACC from the service company owned by the practice's GP principals. It appears to the Department, based on data analysis and modelling, that the rent paid by the provider for those premises is an outlier rent.

To understand the reasons for this, the Department writes to both the service company and the provider requesting further information about the rent. (The service company is "connected" to a requester of pathology services as the GP principals are directors and members.)

The responses received from the service company and provider provide a clear explanation for the rent and are supported by an independent valuation that was obtained by the service company during lease negotiations.

The Department is satisfied by the responses and does not take any further action.

Example 2

A pathology provider has an ACC in a small private hospital. It leases the space occupied by the ACC from the company that has management rights over the small private hospital (hospital manager). It appears to the Department, based on data analysis, that the rent paid by the provider for the space occupied by the ACC is several times more than other providers are paying for comparable spaces in comparable markets.

To understand the reasons for this, the Department writes to both the hospital manager and the provider requesting further information about the rent. (The hospital manager, which credentials visiting medical officers and employs junior medical staff, both of which are requesters of pathology services, is "connected" to a requester of pathology services because of those relationships.)

The responses received from the hospital manager and provider do not explain the reason that the rent is significantly higher than what others are paying. The Department invokes its powers under the Medicare Act and obtains documents from the provider which indicate that it agreed to rent space at a higher (i.e. non-commercial rent) to prevent its competitors from leasing the space. The hospital manager and the provider are unwilling to renegotiate the lease and advise the Department that they regard the arrangement as within the bounds of standard business practice.

The Department, having exhausted avenues to obtain voluntary compliance, commences civil proceedings against both the hospital manager and provider for a contravention of the prohibited practices provisions.

Example 3

A pathology provider leases a consulting room from a sole GP and uses this as an ACC. It appears to the Department, based on data analysis and modelling, that the rent paid by the provider for the consulting room is an outlier rent.

To understand the reasons for this, the Department writes to both the GP and the provider requesting further information about the rent. The responses received do not explain why the rent is out of step with other comparable arrangements, and give the Department reasonable grounds to believe that a contravention of the Prohibited Practices Provisions may have occurred.

The Department uses its investigative powers under the Medicare Act to require the GP and provider to provide the Department with further information about the negotiation of the lease.

It appears from that information that the rent was agreed on the basis that the GP would, as a quid pro quo, direct all of its future pathology referrals to the provider. Neither the GP nor the provider realised that this may contravene the prohibited practices provisions, and on being advised of this, are keen to renegotiate their arrangements to ensure that they comply with the law.

The Department considers that, as the GP and provider are cooperative and that the contravention appears inadvertent, a compliance undertaking would be the most appropriate way to secure the parties' compliance. The Department offers both parties the opportunity to enter into a compliance undertaking in which they among other things agree, within a specified timeframe, to vary the lease to address the level of the rent payable. Variation occurs, and the GP's pathology referral patterns return to that seen previously. The Department does not take any further action.

Example 4

The Provider Benefits Integrity Hotline receives a call from a practice manager who is concerned that, since the clinic in which she works renegotiated its lease with the operator of its co-located ACC, many more patients have been referred for pathology tests.

The Department analyses the information it holds about the ACC and about the clinic. The information indicates that there has been an increase in the volume of pathology referrals and changes in the mix of tests ordered. Both changes followed the renegotiation of the lease. Additionally, the rent paid under the lease is an outlier on the data, and is substantially greater than the rent paid prior to renegotiation.

The Department writes to both the clinic and the pathology provider operating the ACC, requesting further information about the rent. This provides the clinic and the pathology provider with the opportunity to comply voluntarily.

The responses received do not explain why the rent is an outlier. This, combined with the changes to pathology referral volumes, gives the Department reasonable grounds for believing that a contravention of the prohibited practices provisions may have occurred.

The Department uses its investigative powers under the Medicare Act to require the clinic and provider to provide the Department with further information about their broader business arrangements.

The Department decides, on the basis of the information supplied, that there is clear evidence of contravention of the prohibited practices provisions. It commences civil proceedings against both the clinic and provider.