Health Insurance Amendment (Inappropriate and Prohibited Practices and Other Measures) Act 2007

Prohibited Diagnostic Imaging Practices

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Introduction

The Health Insurance Amendment (Inappropriate and Prohibited Practices and Other Measures) Act 2007 was enacted in June 2007. This legislation clarifies and strengthens prohibitions in the Health Insurance Act 1973 (the Act) against inappropriate inducements to request diagnostic imaging services or pathology services. The amendments will come into effect from 1 March 2008.

The amendments are designed to:
- prohibit certain practices in relation to the rendering of diagnostic imaging and pathology services, including prohibiting inducements and other relationships between requesters and providers of those services;
- prevent payments for diagnostic imaging and pathology services that do not benefit patients; and
- encourage fair competition between providers of diagnostic imaging and pathology services on the basis of quality of service provided, and cost to patients.

The Act provides for the development of subordinate (secondary) legislation to support it. This secondary legislation will determine specified permitted benefits, and prescribe a method for determining market value.

Purpose of this paper

The legislation prohibits a provider of diagnostic imaging or imaging services to provide a benefit to a requester of those services, unless the benefit is included in the list of permitted benefits contained in the Act or in a Ministerial determination of permitted benefits. This paper identifies a number of kinds of benefits, notes whether the Department currently considers they should or should not be included in the list of permitted benefits and what criteria should apply, and explains the principles underlying these views.

Under the legislation, some kinds of benefits are permitted benefits only if the amount of the benefit is not substantially different from the market value of what is exchanged. The legislation allows for regulations to be made prescribing a method for determining market value, and of working out whether the amount of a payment is substantially different from the market value. This paper outlines the approach to these issues.

The purpose of this paper is to seek input from stakeholders on the following matters:

- what benefits should be included in the Ministerial Determination of permitted benefits’ in relation to diagnostic imaging;
- the proposed method for determining ‘market value’ of property, goods or services; and
the proposed method for working out whether a payment is ‘substantially different’ from the market value.

This paper has been developed by the Department of Health and Ageing drawing on extensive stakeholder consultations.

Submissions

Stakeholders are invited to provide submissions on any issues raised in this paper, including:
- any areas where stakeholders agree or disagree with the Department’s proposed approach;
- any benefits that are not discussed in this paper that stakeholders consider should be included as permitted benefits; and
- any areas where stakeholders consider that the proposed position would, if adopted, impose unreasonable or unnecessary costs on business.

Submissions should be made by 25 January 2008.

Submissions should be sent to:
Email: legislativeamendments@health.gov.au
or
Mail: Prohibited Practices
Diagnostics and Technology Branch
Department of Health and Ageing
MDP 107
GPO Box 9848
CANBERRA ACT 2601

Stakeholders should ensure that they include the following information in their submissions:
Name
Contact address
Contact email
Organisation on whose behalf the submission is made (if applicable)

The consultation process is open to public scrutiny, and any submissions received will also be published on the Department’s website. If you wish any information contained in a submission to remain confidential on commercial grounds, please let us know when you lodge your submission.
Part 1. Permitted Benefits

The legislation will prohibit a provider of diagnostic imaging services to provide a benefit to a requester of those services, unless the benefit is included in the list of permitted benefits contained in the Act or in a Ministerial determination of permitted benefits.

1.1 Principles

The overarching principle in relation to permitted benefits is that no benefit will be a permitted benefit if it is related to the number, kind or value of requests for diagnostic imaging services made by a requester. Even if a particular benefit meets the other criteria specified in the Act or in a Ministerial Determination, it will not be a permitted benefit if, for example, the benefit will only be provided if the requester agrees to request diagnostic imaging services from a particular provider.

A further guiding principle is that legislative amendments are not intended to prohibit competition between diagnostic imaging providers on the basis of the quality or the cost of service they provide.

The objective of the prohibited practices legislation is to prevent inducements to request diagnostic imaging services. It is considered, that any benefit not permitted by the Act or the Ministerial Determination could have the potential to induce services. This is also an important factor in considering the benefits to be included in the Ministerial Determination.

Where a particular benefit is not covered by the Ministerial Determination, it does not necessarily mean that the benefit is in breach of the legislation. Whether or not it is a permitted benefit will depend on whether it complies with the relevant provisions in the Act and the regulations. However, if a particular benefit is covered by the Ministerial Determination, then asking for, offering, accepting or providing that benefit will not be a breach of the legislation.

The fact that a particular benefit may be covered by the Ministerial Determination of permitted benefits does not mean that diagnostic imaging providers are expected or obliged to provide such benefits, nor that requesters are expected or obliged to accept them.

1.2 Proposals

The legislation permits the inclusion of additional permitted benefits in secondary legislation. The Department is seeking input from stakeholders on proposals relating to the following benefits:

- Education
- Diagnostic Imaging Support Items, eg requesting software, light boxes
- Marketing
- Stationing of staff or diagnostic imaging equipment at the premises of a requesting practitioner
- Discounted fees and charges for diagnostic imaging services
- Leasing of Property
- Hospitality and gifts
1.2.1 Education

Providers are well placed to provide appropriate, relevant and targeted educational information to assist requesters to make efficient and effective use of diagnostic imaging services.

Proposal

The Department therefore proposes that it should be a permitted benefit for a requester to be provided with free educational material about diagnostic imaging, including the provision of information that may be passed on to patients.

The Department also proposes that it should also be permitted for a provider to host relevant education sessions on diagnostic imaging for requesters and their staff. This may include the provision of modest hospitality. The Department suggests that hospitality would be considered modest if its cost was no more than $100 per person per day.

Free education sessions (including associated hospitality) would be permitted benefits where:

- the primary objective of the event is to provide relevant information about diagnostic imaging;
- any hospitality is secondary to the educational purpose of the event;
- the venue is appropriate for the educational purpose of the meeting;
- travel and accommodation costs, if any, are not met by the provider; and
- the event does not include and is not held in conjunction with any sporting event or other entertainment.

In developing these criteria, the Department has referred to the Medicines Australia Guidelines to Code of Conduct Edition 15.

Areas where the Department suggests that it would be appropriate to provide educational material and education sessions would include:

- appropriate requesting of diagnostic imaging services, including the most appropriate imaging modality for the clinical condition of the patient; and
- understanding reports for the different diagnostic imaging modalities.

The Department welcomes comments on the proposal regarding educational materials and sessions.

1.2.2 Diagnostic Imaging Support Items

The Department understands that diagnostic imaging service providers often provide diagnostic imaging related items to assist requesters in either reading films/images or making requests, eg light boxes, requesting software and digital imaging reading software.

Proposal

It is proposed that providing items free of charge (and irrespective of their value) to a requester be a permitted benefit as long as they are of a type that can either be soley used
for the purpose of diagnostic imaging or are provided primarily for that purpose. For example, it would be permissible to provide CDs containing requesting or viewing software, but it would not be permissible to provide a computer system, since the computer system can be used for other purposes. Similarly, it would be permissible to provide special monitors to enable requesters to view images if that was the primary purpose of the monitors.

The Department would welcome submissions on the proposal regarding diagnostic imaging support items.

### 1.2.3 Marketing

**Principle**

The legislative amendments are not intended to prohibit competition between diagnostic imaging providers on the basis of the quality or the cost of service they provide.

**Proposal**

The Department therefore proposes that it should be a permitted benefit for a diagnostic imaging provider to provide promotional publications and promotional items of token value to requesters, free of charge. This may include material promoting the quality, convenience and cost to patients of the provider’s service. To avoid creating an opportunity for gifts to be disguised as promotional items, any marketing material would need to be clearly identified as coming from the diagnostic imaging provider, for example, bearing its corporate brand.

The Department would welcome submissions on whether there should be a dollar value limit on promotional items and, if so, what the limit should be.

### 1.2.4 Stationing of staff or equipment at the place of a requesting practitioner

Under the current prohibited diagnostic imaging practice provisions of the Act, it is unlawful for a provider of diagnostic imaging services to station diagnostic imaging equipment or staff in the premises of a requesting practitioner. There is an exception to this rule where the requester’s practice is in a remote area. A remote area is currently defined as a location that is more than 30 kilometres from an imaging practice or hospital under the direction of a specialist radiologist. This definition of remote area is used for a number of other Medicare rules for diagnostic imaging services, for example the professional supervision rules. The remote area definition was first introduced in 1991 for general practitioners self referring for R-type diagnostic imaging services. The exemption for stationing of staff or equipment at a requester’s premises in a remote area was introduced in 2003.

In order to gain an exemption to station staff or equipment at a requester’s premises, the provider is required to apply to Medicare Australia, and then reapply every three years.
The current legislative provisions covering this prohibition and exemptions are paragraph 23DZG(1)(g), subsection 23DZG(2) and a number of sections in Division 2 of Part IIB.

The prohibition on stationing staff or equipment at a requester’s premises has been preserved under the new legislation under paragraph 23DZZIF(7)(b). However, we did not keep the exemption provisions as part of the new amendments. Instead (and as indicated during our consultations leading up to the introduction of the legislation), it is intended that stationing staff or equipment in a requester’s premises in a remote area could be listed in the Ministerial Determination of permitted benefits.

Before we go on to discuss exemptions to the general prohibition, it would be helpful to describe how the prohibition relates to the permitted benefit in the amended Act that allows providers to lease rooms from requesting practitioners as long as this rental is not substantially different from the market rate. Subsection 23DZZIF(5) is the applicable section in the amended Act.

Where the provider has rented rooms from the requester and stationed staff and/or equipment in these rooms, subsection 23DZZIF(5) applies. That is, such arrangements are permitted if the rent paid for the rooms is not substantially different to the market rate.

The prohibition on the stationing of staff or equipment at a requester’s premises only applies where the staff or equipment is stationed in the requester’s own rooms.

Mobile services

It is understood that a common business arrangement for mobile services is where the provider leases rooms in medical clinics and/or hospitals on a sessional basis. The Department would see this as a leasing arrangement subject to subsection 23DZZIF(5).

Hospital operating theatres

The Department is aware of business arrangements whereby independent radiology providers may either own the diagnostic imaging equipment located in hospital operating theatres and/or provide the staff to operate the equipment.

The Department is of the view that such arrangements should be permitted as long as the commercial arrangements entered into between the hospital and the radiology provider are not substantially different from the market rate.

In developing the provisions under the permitted benefit determination for the stationing of staff or equipment at a requester’s premises, it may be an appropriate time to reassess the appropriateness of the existing remote area exemption. The Department understands that there have been no applications for a remote area exemption to station staff or equipment at the place of a requesting practitioner since the exemption was introduced in 2003. However, if we did continue with having the exemption provisions, perhaps we could also consider the current relevance of the 30km rule and the administrative processes that providers and Medicare Australia need to go through in seeking and approving exemptions.

The Department would welcome comments on the following matters:
− whether the existing exemption arrangements are still appropriate
− is the 30km rule for determining remote areas still relevant or should there be some other measure
− should it be necessary for practices to have to formally apply for a remote area exemption, or should this be dealt with in other ways, for example, through other compliance activity
− arrangements involving mobile services and the stationing of staff and or equipment in operating theatres.

1.2.5 Discounted fees and charges for diagnostic imaging services

The Department understands that, as a professional courtesy, a provider may wish to provide free or discounted diagnostic imaging services where the patient is a person connected to the requester, such as a family member.

Principle

The legislation is not intended to prohibit competition by providers on the basis of the quality or the cost of service they provide.

Proposal

It has been suggested that providing diagnostic imaging services to requesters and persons connected to them free of charge or at a discounted fee be a permitted benefit.

The Department seeks comments on whether providing free or discounted diagnostic imaging services to requesters and persons connected to them should be a permitted benefit.

1.2.6 Transactions above or below the market rate in certain circumstances

Under subsections 23DZZIF(4) and (5), a transaction is only permitted if the payment or consideration for the property, goods or services are not substantially different from the market rate (see Part 2 for a discussion on the market rate).

Transactions substantially different from the market rate are prohibited as this could be a way to disguise an inducement. For example, a diagnostic imaging provider might lease premises from a requester for higher than the market rate or conversely, a provider might lease clinical rooms to a requester for less than the market rate as a method of providing indirect inducements to the requester. As another example, a provider may pay less than their share of the cost of staff or equipment shared with a requester.

There may be circumstances however, where paying an amount above or below the commercial rate should be permitted. Taking the lease example above, should it be appropriate for a provider to pay less than the market rate for a lease? Paying less than the market rate in such circumstances would not be expected to potentially induce the requesting of services.
The Department seeks comments on whether it is appropriate that transactions involving the payment of benefits that are substantially different from the market rate be permitted in the circumstances such as described above.

### 1.2.7 Leasing of property

The Department understands that sometimes diagnostic imaging providers lease property from requesters, particularly to use as diagnostic imaging premises. To give parties to such leases the opportunity to assure themselves that their arrangements are permitted benefits, it is proposed that a Ministerial Determination would specify particular circumstances in which lease payments would be permitted benefits.

**Proposal**

It is proposed that payments for leases of property will be permitted benefits in the following circumstances:

- Either of the parties to the lease have obtained at least two sworn valuations of the market value of the lease arrangement, by a valuer applying the criteria in the regulations (see next section of this paper). Note: one party could obtain two valuations or the parties could obtain one each;
- the sworn valuations were obtained from persons who are at arm’s length from the participants to the lease (or persons connected to them – as defined in the Act);
- the valuers are:
  - registered, accredited, certified or otherwise recognised as a valuer under any relevant State or Territory legislation; or
  - recognised as a valuer by the Australian Property Institute;
- the payments under the lease are not substantially different from the market value, calculated as outlined below (i.e. are within 10% above or below the average of all valuations obtained);
- where the premises are leased by a provider of pathology services, an approved collection centre or accredited pathology laboratory is established within 60 days after the lease commences, or the provider renders professional services in the premises; and
- the lease, and any rights, obligations or payments under the lease, are not linked to the number, kind or value of requests for pathology and diagnostic imaging services made by the requester.

For leases entered into before 1 March 2008, it is proposed that the parties will be able to obtain valuations up to 1 September 2008.

Where a lease is for more than three years, it is proposed that the valuations would need to be obtained by the third anniversary of the lease and each third anniversary thereafter.

Similar provisions would apply to licences to occupy and other rental type arrangements.

There will be no requirement that parties to a lease obtain valuations. If the parties to a lease have not taken these steps to ensure that their lease payments are permitted
benefits, the lease may nevertheless still comply with the legislation if the rent is not substantially different from the market value, determined in accordance with the regulations. The parties will not be required to provide these leases to Medicare Australia unless requested to do so.

The Department seeks comments on the proposal that the leasing of property be listed as a permitted benefit in the circumstances described above.

1.2.8 Hospitality and Gifts

Apart from the exceptions noted under sections 1.2.2 and 1.2.3, the Department does not propose that any other kinds of hospitality or gifts would be included in the list of permitted benefits.

This is because it is difficult to determine a threshold value for the provision of hospitality or gifts at which it could reasonably have the potential to induce the requesting of services.

The Department seeks comments as to whether there are any circumstances (other than those described in sections 1.2.2 and 1.2.3 are appropriate.

Part 2 Market value

2.1 Introduction

Under the amended Act, certain kinds of benefits are permitted benefits only if the amount of the benefit is not substantially different from the market value of what is exchanged. The Act allows for regulations to be made prescribing a method of working out what the market value is, and whether the amount of a payment is substantially different from the market value.

2.2 Determining the market value

Market value has an accepted meaning in common law and is a concept used in a range of existing regulations.

Proposal

The Department proposes that the approach to determining market value in the regulations should be based on these existing common law provisions.

In general, it is proposed that regulations would provide that the market value of a benefit be determined by obtaining valuations on the following basis:

1. the amount that a willing, but not anxious, buyer of the property, goods or services could reasonably be expected to pay to acquire the property, goods or services from a willing, but not anxious, seller assuming:
   - the sale occurred after appropriate marketing;
   - the sale occurred on an ordinary commercial basis, without any discount or incentive for purchase;
• there is a reasonable period in which to negotiate the sale;
• the buyer and seller dealt with each other at arm’s length in relation to the sale;
• the buyer and the seller acted knowledgeable and prudently in relation to the sale;

2. not taking into account:
• any special value to the seller;
• any other special interest or concern of the buyer or seller, including the availability of concessions, incentives or inducements to purchase or sell (if any) that are not available to all participants in the marketplace for comparable property, goods or services;
• the costs of disposing of property or goods or the engagement of the person to deliver the services;
• any anticipated, likely or possible effect on requesting of pathology or diagnostic imaging services by any requester; and

3. taking into account relevant market information, such as information about other actual sales, where those sales are a representative sample and reflect the approach outlined above, and do not include information about sales involving parties with a special interest, such as information about the price that a provider of pathology services might pay for proximity to a source of requests.

While the inclusion of specific reference to pathology and diagnostic imaging requests would be specific to these regulations, it reflects the accepted legal concept of market value, which excludes factors particular to the people involved in a transaction.

It is proposed that the value of a lease or property would not be adjusted to reflect any additional value that any party to the arrangement might attribute to this space because of its proximity or convenience to any source of pathology or diagnostic imaging requests. This reflects the accepted legal meaning of market value. It is intended to ensure that lease payments are paying only for actual property costs and not for the value of any possible diagnostic imaging requests. As noted above, the legislative amendments also provide that a benefit is not a permitted benefit if it is related to the number, kind or value of requests made by a requester.

The Department seeks comment on the proposed method for determining the market value.

2.3 Valuations

Principle

It will not be compulsory to obtain valuations. Where the parties do choose to obtain valuations, the Department considers that two valuations would provide each party to the transaction with the opportunity to obtain their own valuation and reduce the potential for the market valuations to be improperly skewed by one party.
2.3.1 Parties who have obtained valuations

Proposal

It is proposed that where the parties have obtained two sworn valuations from appropriately qualified and arms-length valuers before entering into the transaction, the market value of the transaction for the purpose of the regulations would be the average of those two valuations. If the transaction continues over an extended period, updated valuations would need to be obtained every three years. For transactions entered into before 1 March 2008, we are proposing that the valuations would need to be obtained by 1 September 2008.

It is proposed that the regulations would also provide that parties to a transaction must provide any relevant valuations and lease documents to Medicare Australia on request within 60 days. If a practice doesn't provide the documents, Medicare Australia can obtain its own valuation (see section 2.3.2).

2.3.2 Parties who have not obtained valuations

Proposal

It is proposed that where the parties do not obtain their own valuations prior to entering into a transaction, Medicare Australia would be able to require a party to obtain a valuation if Medicare Australia had a reasonable belief that a breach of a civil penalty provision or a criminal offence had been, or was being, committed. In this circumstance, a party would have 60 days to obtain a valuation and provide it to Medicare Australia.

Where no valuations are provided to Medicare Australia, or the valuations provided are not from appropriately qualified valuers or are otherwise not in accordance with the regulations, then Medicare Australia would be able to obtain its own valuation from an appropriately qualified valuer. The market value of the transaction would be the value advised to Medicare Australia. It is proposed that the regulations would allow a valuer making a valuation for Medicare Australia to make reasonable assumptions about the transaction in question where he or she was not able to view the relevant property, goods or services in person.

2.4 Qualifications of valuers

2.4.1 Real estate, including leases

In relation to real estate, including leases, it is proposed that the valuer would need to be:

- registered, accredited, certified or otherwise recognised as a valuer under any relevant State or Territory legislation; or
- recognised as a valuer by the Australian Property Institute.

2.4.2 Other property, goods or services

For other transactions, it is proposed that valuers be registered, accredited, certified or otherwise recognised as a valuer in respect of the particular kind of property, good, or
The Department invites comment on the proposals regarding valuations.

2.5 “Substantially Different” from the Market Value

Background

It is proposed that the regulations will also specify when the amount of a payment, or of consideration, is substantially different from the market value of the benefit in question.

Principle

The definition of ‘substantially different’ should provide sufficient scope to allow for legitimate differences in value, without allowing so much latitude that a benefit could be used to conceal an inducement.

As a general rule, it is proposed that a payment or consideration that is either above or below the market value (determined as described above) by more than 10% would be regarded as substantially different from the market value.

Proposal

It is proposed that the regulations will specify that the payment or consideration provided for property, goods or services is substantially different from the market value if:

- at least two valuations of the property, goods or services, calculated as described above, have been obtained from independent valuers with appropriate expertise or accreditation and not connected to any party to the transaction, within the last three years;
- the average of those valuations is subtracted from the amount of the payment or consideration;
- that difference is divided by the market value and expressed as a percentage; and
- the resulting percentage is more than 10%.

If Medicare Australia has obtained its own valuation, as described above, then the payment or consideration would be substantially different from the market value if it is more than 10% above or below the valuation obtained by Medicare Australia.

The Department invites comment on the proposal that substantially different from the market value is more than 10% above or below the market value as valued by approved valuers.