



Australian Government

Department of Health and Ageing

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

Prohibited Pathology Practices

Discussion Paper

CONTENTS

INTRODUCTION	3
PURPOSE OF THIS PAPER	3
SUBMISSIONS	4
PART 1 PERMITTED BENEFITS	5
1.1 Specimen Collection	6
Background	6
1.1.1 Equipment	6
1.1.2 Consumables	6
1.1.3 Sharps disposal	7
1.2 Education	8
1.3 Marketing	9
1.4 Transactions above or below the market rate in certain circumstances	9
1.5 Leasing of property	10
1.6 Hospitality and Gifts	11
PART 2 MARKET VALUE	12
2.1 Market Value of Property, Goods or Services	12
2.1.1 Valuations	13
2.1.2 Qualifications of valuers	14
2.2 Substantially Different from the Market Value	15

Introduction

The *Health Insurance Amendment (Inappropriate and Prohibited Practices and Other Measures) Act 2007* was enacted in June 2007 to clarify and strengthen prohibitions in the *Health Insurance Act 1973* (the Act) against inappropriate inducements to request pathology or diagnostic imaging 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 pathology and diagnostic imaging services, including prohibiting inducements and other relationships between requesters and providers of those services;
- prevent payments for pathology and diagnostic imaging services that do not benefit patients; and
- encourage fair competition between providers of pathology and diagnostic imaging services on the basis of quality of service provided, and cost to patients.

The legislation also provides for subordinate (secondary) legislation to be made to support the Act.

It is important to note that even if a commercial arrangement such as a lease or contract has been entered into before the new provisions take effect, it may still be in breach of the legislation if it does not meet the new requirements. It is expected that it will be necessary to renegotiate commercial arrangements, in some cases, to bring them in line with the new legislative requirements.

Purpose of this paper

The legislation prohibits a provider of pathology or 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. 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 proposed approach to these matters.

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

- what benefits should be included in the list of 'permitted benefits' in relation to pathology; and
- the proposed method for determining 'market value' of property, goods or services and of working out whether a payment for property, goods or services is 'substantially different' from the market value.

Submissions

Stakeholders are invited to provide submissions on any issues raised in this paper, including:

- 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
- areas where stakeholders consider that the proposed position would, if adopted, impose unreasonable or unnecessary costs on business.

Submissions should be sent or emailed by **25 January 2008** to:

Ms Hilary Metcalf
Director
Pathology Section
Diagnostics and Technology Branch
Department of Health and Ageing
MDP 107
GPO Box 9848
CANBERRA ACT 2601
legislativeamendments@health.gov.au

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 pathology or 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.

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 pathology services or 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 make pathology requests from a particular pathology provider.

Where a particular benefit is not covered by the Ministerial determination, this does not necessarily mean that it 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 pathology providers are expected or obliged to provide such benefits, nor that requesters are expected or obliged to accept them.

Proposal

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

- specimen collection
 - equipment
 - consumables
 - sharps disposal
- education
- marketing
- leasing of property, including approved collection centres
- gifts and hospitality

1.1 Specimen Collection

Background

Pathology providers are currently permitted to provide requesting practitioners with free specimen collection items listed in the Approved Pathology Practitioner and Approved Pathology Authority undertakings. It is expected that this list will be removed from the undertakings once the legislative amendments take effect. Instead, pathology providers will be permitted to provide requesting practitioners with specimen collection items of a kind that are permitted benefits under the Ministerial determination, or which are supplied on terms which otherwise meet the requirements of the Act and regulations.

1.1.1 Equipment

Principle

In order to ensure the quality of testing, there are particular items of equipment that may be necessary to ensure that the specimen is correctly collected, identified and stored.

Proposal

The Department proposes that it should be a permitted benefit to provide (free of charge) at a practitioner's premises, equipment that is related **exclusively** to the collection, identification and temporary storage of pathology specimens and is not used for any other purposes.

For example, it would be a permitted benefit to provide a single bleeding chair that was used only for the collection of pathology specimens, or to provide a fridge that was used only to store pathology samples awaiting transport.

The Department notes that a disadvantage of this approach is that whether a benefit is a permitted benefit may depend on how the requester uses it after it has been provided.

1.1.2 Consumables

Principle

The Department suggests that the reason for allowing pathology providers to supply requesting practitioners with certain free consumables is to ensure the quality of specimens collected at the practice and the safety of the specimen collection. GPs are now obliged by accreditation standards to have specimen collection equipment (see Royal Australian College of General Practice Standards for General Practices 3rd Edition, Criterion 5.2.1).

Proposal

The Department is considering whether it should be a permitted benefit for a requester to be provided free of charge with goods that are:

- used to collect a specimen or sample for pathology testing and disposed of after they have been used for this purpose; or
- goods whose use contributes to the safety of the patient and/or the health professional taking the sample, or the appropriate identification, storage, transport and testing of the sample and are disposed of after they have been used for this purpose.

The number provided should be not greater than would be needed for the number of pathology specimen collections that would usually be undertaken by a practice of that size.

Examples of items that would meet these criteria would be specimen containers and needles which are used by the requesting practitioner for the collection of pathology specimens.

1.1.3 Sharps disposal

Principle

The appropriate disposal of used sharps is an important consideration in the safety of specimen collection for both patients and health professionals.

Proposal

Stakeholders have proposed to the Department that it should be a permitted benefit for a requester to be provided with sharps disposal services, including sharps containers. If provided as a permitted benefit to allow safe disposal of needles used in the collection of pathology specimens, it has been suggested that the sharps disposal service should also be used for the disposal of any other sharps generated by the practice, as it would be inefficient to require a practice to maintain a separate additional sharps disposal service.

The Department notes, however, that as it is efficient for a practice to use a single sharps disposal service, only one pathology provider would be able to provide this benefit for a practice, unlike the consumables and equipment discussed above. It is possible that if doctors were provided with a sharps disposal service by a particular pathology provider, they might feel a moral obligation to refer to that provider.

The Department invites comments on:

- whether provision of specimen collection items by pathology providers is necessary or appropriate; and, if so
- whether the principles described in sections 1.1.1, 1.1.2 and 1.1.3 to define the types of items which would be permitted benefits are appropriate;
- whether requesters and providers would be able to put in place appropriate arrangements to ensure that equipment is not used for other purposes; and
- how the concerns discussed might be addressed.

1.2 Education

Principle

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

Proposal

The Department therefore proposes that it should be a permitted benefit for a requester to be provided with free educational material about pathology, 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 pathology 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 pathology;
- 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 pathology tests;
- understanding results and reports for different areas of pathology and for particular tests; and
- specimen collection, identification and transport procedures.

<p>The Department invites comments on the proposal regarding educational materials and sessions.</p>

1.3 Marketing

Principle

The legislative amendments are not intended to prohibit competition between pathology 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 pathology provider to provide pathology request forms, 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 pathology provider, for example, bearing its corporate brand.

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

1.4 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.

1.5 Leasing of property

The Department understands that a common transaction between pathology providers and requesters is the leasing of property, particularly to use as an Approved Collection Centre. 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.

Apart from leases involving approved collection centres (see below), 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.

Approved collection centres

It is proposed that the application for an Approved Collection Centre (ACC) will no longer require the inclusion of details about the rent paid. Instead, the Department is considering requiring the applicant Approved Pathology Authority (APA) to advise whether or not the ACC is leased from a requester or from a person connected to a requester. Where it is, then it is proposed that the APA will need to confirm that two appropriate valuations have been obtained and that the lease is not substantially different from the market value, in line with the above. Where the application is submitted between 1 March and 1 September, the APA would need to confirm that appropriate valuations will be obtained before 1 September. If the APA does not confirm that appropriate valuations have been, or will be, obtained, then the ACC licence would not be approved.

It is proposed that the regulations would also provide that parties to an ACC lease must provide any valuations, as well as the lease, to Medicare Australia on request. Failure to do so would be a possible breach of the APA undertaking. This would give Medicare Australia the power to conduct random audits to confirm that the lease payments are not substantially different from the market value.

The Department invites comments on the proposals in relation to the circumstances in which leasing of property will be a permitted benefit.

1.6 Hospitality and Gifts

Apart from the exceptions noted in section 1.2 and 1.3 above, the Department does not propose that any other kinds of hospitality or gifts would be included in the list of permitted benefits.

The Department invites comments on whether there are circumstances in which the provision of hospitality is appropriate.

Part 2 Market value

2.1 Market Value of Property, Goods or Services

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.

Principle

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

- 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 knowledgeably and prudently in relation to the sale;
- 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
- 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.

Proposal

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 a provision that is currently included in prohibited practices provisions of the Act in relation to pathology, as well as 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 pathology 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.

2.1.1 Valuations

Principle

Valuations will only be mandatory where a pathology provider leases a property used for an Approved Collection Centre from a requester. For all other transactions, valuations are optional. 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 valuation to be improperly skewed by one party.

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 documents to Medicare Australia on request within 60 days.

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. 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.

2.1.2 Qualifications of valuers

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.

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 service under any relevant State, Territory or Commonwealth legislation, for example, the Income Tax Assessment Act.

<p>The Department invites comments on the proposals regarding market value and valuations.</p>

2.2 Substantially Different from the Market Value

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.

Proposal

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.

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 comments on this proposal.