**EXPLANATORY STATEMENT**

***HEALTH INSURANCE ACT 1973***

***Health Insurance (Permitted Benefits - Pathology Services) Determination 2018***

The *Health Insurance (Permitted Benefits – Pathology Services) Determination 2018* (the Determination) is made under section 23DZZIG of the *Health Insurance Act 1973* (‘the Act’).

The purpose of the Determination is for the Minister to determine benefits that would otherwise be unlawful under the Act, to be permitted benefits in relation to pathology.

The *Health Insurance (Permitted benefits - pathology services) Determination 2008* (the previous Determination) is due to sunset on 1 April 2018 due to the sunsetting provisions in the *Legislation Act 2003*. It is remade with minor drafting changes.

The Act provides for payments of Medicare benefits in respect of professional services rendered to eligible persons. Part IIBA of the Act deals with prohibited practices in relation to pathology services and diagnostic imaging services.

Part IIBA of the Act regulates behaviour whereby providers (or persons connected with them) offer or provide benefits to requesters (or persons connected with them). It also regulates behaviour whereby requesters (or persons connected with them) seek or accept benefits from providers (or persons connected with them). Such behaviour may be prohibited by the Act unless the benefit in question is a “permitted benefit”. The Act prescribes a number of benefits which are permitted, and these generally relate to transactions that are of an arm’s length bona-fide commercial nature. This Determination provides, in relation to pathology services, for a specified class of benefits that would otherwise be unlawful under the Act, to be permitted benefits. A separate determination applies in relation to diagnostic imaging services.

In summary, the types of benefits permitted under this Determination are:

* items that help requesters to make requests or view pathology reports, for example computer software for electronically submitting requests or receiving results;
* stationing staff or equipment in a hospital or at a requester’s clinical rooms during surgical procedures;
* educational material;
* educational sessions;
* reasonable, infrequent gifts and hospitality;
* promotional material;
* defined goods used in collecting or in relation to collection of pathology specimens (for example, specimen collection containers and needles); and
* defined equipment necessary for the collection, identification or temporary storage of specimens.

Consistent with the previous Determination, providers of pathology services are under no compulsion to provide the benefits included in the Determination. This is a business decision for providers. The Determination simply makes it lawful under the Act if providers do supply them.

Review of the previous Determination identified that the provisions remain appropriate and required only small formal drafting updates.

Subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to support the revocation and remake of this Determination under section 23DZZIG of the Act. Subsection 33(3) is an interpretation rule providing that the power to make an instrument includes the power to repeal and remake the instrument.

The Determination is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Determination commences on the day after it is registered.

Details of the legislative instrument are set out in Attachment A.

**Consultation**

The Department of Health consulted with the Department of Human Services on the making of this instrument.

**ATTACHMENT A**

**Details of the *Health Insurance (Permitted Benefits - Pathology Services)***

***Determination 2018***

**1. Name**

Section 1 provides that the title of the instrument is the *Health Insurance (Permitted Benefits - Pathology Services) Determination 2018.*

**2. Authority**

This section provides that section 23DZZIG of the *Health Insurance Act 1973* is the authority for the instrument.

**3. Commencement**

This section provides for the instrument to commence the day after the instrument is registered on the Federal Register of Legislation.

**4. Repeal**

This section provides that the *Health Insurance (Permitted benefits – pathology services) Determination 2008* is repealed.

**5. Definitions**

This section relates to definitions. It lists examples of terms used in the instrument that, in accordance with statutory conventions, take their meaning from the Act.

**6. Permitted benefits for pathology services**

Under section 23DZZIG of the Act, the Minister may by legislative instrument determine that a specified class of benefits that are asked for or accepted by, or offered or provided to a specified class of persons, be permitted benefits. Subsection 6(1) provides that the benefits listed in Schedule 1 are permitted benefits, subject to subsection 6(2), where:

* a requester (or a person connected to the requester) asks for, or accepts the benefit from, a pathology provider (or a person connected to the provider); or
* a pathology provider (or someone connected to them) offers to or provides the benefit to a requester (or someone connected to the requester).

The concept of a person being “connected” to another takes its meaning from section 23DZZIJ of the Act.

Subsection 6(2) provides that even if a benefit is listed in Schedule 1, it is not permitted if it is related to the number or type or value of requests to a particular provider made by a requester or if it exceeds the normal supply for the needs of the practice over a given time. For example, it would not be permitted to only supply computer software for requesting pathology services on the proviso that the requester ordered a certain number of services. Similarly, the supply of the benefits should be directly proportional to the needs of the requester.

**Schedule 1 Permitted benefits**

This Schedule lists those benefits that are permitted benefits.

**Item 1**

Pathology providers often provide pathology related items to assist requesters to request services or read reports, for example computer software to enable electronic requesting and the receiving of results.

This item provides that it is a permitted benefit for a provider to provide items free of charge (and irrespective of their value) to a requester as long as they are of a type that can only beused for purposes connected with pathology.

For example, it would be permissible to provide CDs containing requesting or receiving software.  However, it would not be permissible to provide a full computer operating system, since the operating system is not something that can only be used for pathology related activities.

**Items 2 and 3**

Paragraph 23DZZIF(7)(b) of the Act prohibits the stationing of staff or equipment at a requester’s premises for the purposes of providing pathology services.

It is regarded as appropriate clinical practice for a provider to station staff and/or equipment in certain clinical settings where it is in the best interests of the patient for requesting practitioners to have a pathologist or pathology scientist available.

For example: in hospital operating theatres, there is often a need to station blood gas analysers for monitoring purposes during operative procedures; in breast clinics it is sometimes necessary for biopsies to be taken for immediate examination by a pathologist.

These items permit a provider of pathology services to station staff at a hospital to collect pathology specimens from patients of the hospital if necessary.  They also permit:

* the stationing of pathology practitioners and any necessary equipment at the premises of a requesting practitioner to provide preliminary analysis or advice in relation to a pathology specimen collected during the procedures listed, ie fine needle biopsies, bone marrow biopsies by aspiration or trephine; or an examination of a frozen section; and
* the stationing of equipment in a hospital, for example blood gas analysers.

**Items 4 and 5**

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

Item 4 makes it a permitted benefit for a provider to supply free educational material about pathology, including information that may be passed on to patients.

Item 5 makes it a permitted benefit for a pathology provider to host relevant education sessions on pathology for requesters and their staff where:

* the primary objective of the event is to provide relevant information about pathology, for example, to discuss appropriate requesting of services or understanding reports of pathology services;
* the venue is appropriate for the educational purpose of the meeting;
* any hospitality is secondary to the educational purpose of the event and the cost of any hospitality provided is reasonable having regard to the venue and conduct of the event.  For example, if the event is a formal seminar in an expensive hotel, it would be reasonable to pay more for hospitality than if the event was a small meeting held in the offices of the provider;
* the participant’s 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.

The provisions in the Medicines Australia Guidelines to Code of Conduct Edition 15 covering conduct of activities between pharmaceutical companies and health practitioners were considered in the initial development of the above criteria. Although there is an Edition 18 of the Code of Conduct Guidelines, the principles relating to conduct of activities continue to be of relevance and aligned.

**Item 6**

This item permits the provision of gifts or hospitality only if:

        they are not cash or convertible to cash, for example shares;

        they are provided infrequently and only for a significant occasion, for example, flowers for a condolence tribute or hospitality at Christmas; and

        they are not given as an inducement, consideration or reward for requesting services.  For example, it would not be in order for a provider to discriminate between large and small volume requesters; and

        the cost of the gift or hospitality is reasonable in the circumstances.  For example, it would be reasonable to provide a modest hamper at Christmas, but it would be inappropriate to give the requester a case of expensive alcoholic spirits.

**Item 7**

This item permits a pathology provider to promote their business with requesters through the provision of request forms and other promotional material, as long as the material being provided is labelled as coming from the provider and has no resale value to the recipient of the benefit.

The purpose of requiring the material to be identified is to avoid creating the opportunity for gifts to be disguised as promotional items.

**Items 8 and 9**

It is extremely important that the pathology specimens are correctly and safely collected, identified and, if necessary, temporarily stored at the requester’s premises before they are transported to the pathology laboratory.

Item 8 prescribes the equipment that can be provided and the conditions under which they can be provided, for example, labelled as coming from the provider.  Item 9 prescribes the goods that can be provided.

The equipment and goods prescribed in Items 8 and 9 mirror those listed in the *Health Insurance (Approved Pathology Undertakings) Approval 2017.*

Essentially, they maintain the pre-1 March 2008 rules for types of equipment and other items that can be provided free of charge to requesters.

**Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

***Health Insurance (Permitted Benefits –Pathology Services) Determination 2018***

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of the Legislative Instrument**

The *Health Insurance (Permitted Benefits – Pathology Services) Determination 2018* (the Determination) sets out certain classes of benefits that are permitted benefits in relation to pathology services, which generally relate to transactions that are of an arm’s length bona-fide commercial nature. This Determination provides, in relation to pathology services, for a specified class of benefits that would otherwise be unlawful under the *Health Insurance Act 1973*, to be permitted benefits.

The *Health Insurance (Permitted benefits-pathology services) Determination 2008* (the previous Determination) is due to sunset on 1 April 2018. This Determination repeals and replaces it, with small formal drafting updates.

**Human rights implications**

The Determination engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights, specifically the rights to health and social security.

The Determination assists in regulating when a Medicare benefit is payable for pathology services. If the Determination is not remade, there will no longer be appropriate exemptions for certain permitted benefits.

The Determination supports access to quality, safe, clinically relevant and cost effective pathology services. The Determination also promotes the right to health by assisting to ensure that providers and requesters of Medicare-eligible pathology services provide safe and high quality services.

**Conclusion**

The Determination is compatible with human rights recognised in the *Human Rights (Parliamentary Scrutiny) Act 2011*.

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