EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health

*Health Insurance Act 1973*

*Health Insurance (Eligible Collection Centres) Approval Amendment (Duration of Approvals) Principles 2018*

Subsection 23DNBA(4) of the *Health Insurance Act 1973*(the Act) provides that the Minister must determine in writing principles to be applied by the Minister in granting approvals for eligible pathology specimen collection centres under subsection 23DNBA(1) of the Act.

Under subsection 16A(5AA) of the Act, in order for Medicare benefits to be payable for a pathology service the pathology specimen must be collected in an approved collection centre (ACC), or in other specified circumstances. The principles relating to the granting of approvals for ACCs under subsection 23DNBA(1) of the Act are the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* (the Principles).

**Purpose**

The purpose of the *Health Insurance (Eligible Collection Centres) Approval Amendment (Duration of Approvals) Principles 2018* (the Amendment Principles)is to amend the Principles to alter the period of duration for which approvals for eligible collection centres are to be granted.

The Principles previously required renewal approvals to be granted for a period of one year, with new approvals to be granted for a period of 6 months. As a result of the changes made by the Amendment Principles, all collection centre approvals will be granted for a period of two years.

The duration of approvals for new ACCs had previously been shortened to six months as an interim measure prior to implementation of changes to the ACC approval regime aimed at better enforcing compliance with the prohibited practices provisions of the Act in relation to certain paymentsfor ACCs.

The Amendment Principles make no changes to matters such as the criteria for the granting of an approval of a collection centre, who may apply for approval or review rights in respect of unsuccessful applications.

The changes to the duration of approvals for eligible collection centres only apply in respect of applications made after the commencement of the Amendment Principles.

The Amendment Principles also repeal redundant transitional provisions.

**Consultation**

The Department consulted extensively on the design of ACC reform options with the pathology and primary care sectors in 2016 and 2017, including the change to the duration of approvals for ACCs.

The Department of Human Services was consulted concerning the impact of the changes on their business operations.

Details of the Amendment Principles are set out in the Attachment.

The Amendment Principles commence on 1 December 2018.

The Amendment Principles are a legislative instrument for the purposes of the *Legislation Act 2003*.

Authority: Subsection 23DNBA(4) of the

 *Health Insurance Act 1973*

ATTACHMENT

Details of the *Health Insurance (Eligible Collection Centres) Approval Amendment (Duration of Approvals) Principles 2018*

Section 1 – Name

# Section 1 provides for the instrument to be referred to as the *Health Insurance (Eligible Collection Centres) Approval Amendment (Duration of Approvals) Principles 2018* (the Amendment Principles)*.*

Section 2 – Commencement

Section 2 provides that the Amendment Principles commence on 1 December 2018.

Section 3 – Authority

Section 3 provides that the Amendment Principles are made under subsection 23DNBA(4) of the *Health Insurance Act 1973*.

Section 4 – Schedules

Section 4 provides that each instrument specified in a Schedule to the Amendment Principles is amended or repealed as set out in the applicable items and any other item in a Schedule has effect according to its terms.

Schedule 1 – Amendments

Schedule 1 provides for amendments to the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* (the Principles).

*Item 1 – subsection 6(3) (including note)*

Item 1 of Schedule 1 provides for the repeal of subsection 6(3) of the Principles and its replacement with new subsection 6(3).

Subsection 6(3) previously provided that all renewal approvals of eligible collection centres were to be expressed to be valid for a period of one year, inclusive of the date of commencement of the approval.

New subsection 6(3) requires that all approvals (new or renewals) granted in respect of an eligible collection centre to be expressed to be valid for a period of two years, inclusive of the date of commencement of the approval.

A note to subsection 6(3) indicates that an approval can be revoked or cancelled under the Act. This previously formed a note to subsection 6(3A).

*Item 2 – subsection 6(3A)*

Item 2 of Schedule 1 provides for the repeal of subsection 6(3A) of the Principles. Subsection 3A provided that an approval granted in respect of an application other than a renewal application must be expressed to be valid for a period of six months, inclusive of the date of approval. This was an interim arrangement which is no longer required.

*Item 3 – subsection 6(5)*

Item 3 of Schedule 1 provides for the repeal of subsection 6(5) of the Principles. Subsection 6(5) defined the meaning of a ‘renewal application’. This definition is now redundant.

*Item 4 – Part 4 Transitional*

Item 4 of Schedule 1 provides for the repeal of Part 4 of the Principles. Part 4 established transitional arrangements to enable applications for approval that were before the Minister at 1 July 2010 to be considered under the Principles rather than under the *Health Insurance (Eligible Collection Centres) Approval Principles 2008*, which were in effect until 1 July 2010. The transitional arrangements are now redundant.

Schedule 2 – Application

Item 1 of Schedule 2 provides that section 6 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* in force immediately before the commencement of the amendments made by Schedule 1 continue to apply to applications for approval made before the date Schedule 1 takes effect. Applications for new approvals made before the amendments to section 6 of the Principles take effect will continue to be granted approvals for a period of six months. Renewal applications made before the amendments to section 6 of the Principles take effect will continue to be granted approvals for a period of one year.

Item 2 of Schedule 2 provides that an application made online is taken to be made at the time the applicant uploads it to the website specified in the prescribed form, an application sent by post will be taken to be made by an approved pathology authority at the time the applicant posts the application to the address specified in the prescribed application form, and applications sent by facsimile will be taken to be made at the time the applicant dispatches it to the facsimile number specified in the prescribed form. The prescribed form is available on the Department of Human Services website.

**Statement of Compatibility with Human Rights**

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

***Health Insurance (Eligible Collection Centres) Approval Amendment (Duration of Approvals) Principles 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* (*Eligible Collection Centres) Approval Amendment (Duration of Approvals) Principles 2018* (the Amendment Principles) amend the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* (the Principles) to alter the period for which approvals of eligible pathology collection centres can be granted.

Under subsection 16A(5AA) of the *Health Insurance Act 1973* (the Act), in order for Medicare benefits to be payable for a pathology service the pathology specimen must be collected in an approved collection centre (ACC), or in other specified circumstances.

Subsection 23DNBA(4) of the Act requires the Minister to determine principles to be applied when granting collection centre approvals under subsection 23DNBA(1) of the Act. These are the Principles. The Principles previously required new approvals to be granted for a period of six months and renewal approvals to be granted for one year. As a result of the changes made by the Amendment Principles, all collection centre approvals will be granted for a period of two years.

The changes made by the Amendment Principles will only apply in respect of applications made after the amendments take effect.

**Human rights implications**

The amendments do not engage any of the applicable rights or freedoms. In assessing the Amendment Principles, consideration was given to the right to the enjoyment of the highest attainable standard of physical and mental health contained in article 12(1) of the International Covenant on Economic, Social and Cultural Rights. The effects of the Amendment Principles are limited to the business interests of persons granted an approval for an ACC. The amendments will not inhibit the rights of natural persons to enjoy the highest attainable standard of physical and mental health.

The amendments do not affect who is entitled to Medicare benefit, or the amount of benefit to which they are entitled.

The amendments to the Principles do not alter the criteria applicable to the granting of an approval of an eligible collection centre, who may apply for an approval or review rights in respect of unsuccessful applications. The amendments will result in a reduction in regulatory burden on approved pathology authorities (APAs) that own and operate ACCs. Biennial applications for ACC approval will deliver administrative efficiencies and will reduce administrative burden to the pathology sector.

The changes made by the Amendment Principles do not affect the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Conclusion**

This Legislative Instrument is compatible with human rights as it does not raise any human rights issues.

**Celia Street**

**Assistant Secretary**

**Diagnostic Imaging and Pathology Branch**

**Medical Benefits Division**

**Department of Health**