

EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health and Aged Care

Health Insurance Act 1973

Health Insurance (Eligible Collection Centres) Approval Amendment (Duration of Approvals) Principles 2016

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 2016* (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 all approvals to be granted for a period of one year. As a result of the changes made by the Amendment Principles, collection centre approvals will be granted for a period of one year:

- (a) where the approval is a renewal of an approval for an ACC being operated on the same premises by the same approved pathology authority; or
- (b) where the application has been made by a different approved pathology authority than that which previously operated the ACC on the premises and the previous approved pathology authority has ceased to be an approved pathology authority entirely, or the previous authority has been involved in a merger or acquisition resulting in the need for the new application.

Collection centre approvals will be granted for a period of six months in all other circumstances.

The duration of approvals for new ACCs is being shortened to six months as an interim measure prior to implementation of proposed changes to the ACC approval regime aimed at better enforcing compliance with the prohibited practices provisions of the Act in relation to certain payments for ACCs. This will ensure that any new ACC established during this period will be subject to the new arrangements within six months.

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 commencements of the Amendment Principles.

Consultation

The change to the duration of approvals for new ACCs forms part of an agreement reached with the pathology sector to introduce provisions within the Act regulatory framework to define the method of calculating ‘market rent’ for ACCs and to the establishment of compliance mechanisms to enforce the new regulations.

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

Details of the Determination are set out in the Attachment.

The Determination commences on 23 August 2016.

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

Authority: Subsection 23DNBA(4) of the
Health Insurance Act 1973

Details of the *Health Insurance (Eligible Collection Centres) Approval Amendment (Duration of Approvals) Principles 2016*

Section 1 – Name

Section 1 provides for the Principles to be referred to as the *Health Insurance (Eligible Collection Centres) Approval Amendment (Duration of Approvals) Principles 2016* (the Amendment Principles).

Section 2 – Commencement

Section 2 provides that the Amendment Principles commence on 23 August 2016.

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)

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

Subsection 6(3) previously provided that all 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) provides that an approval granted in respect of a ‘renewal application’ (see item 2) for an eligible collection centre must be expressed to be valid for a period of one year, inclusive of the date of commencement of the approval.

New subsection 6(3A) provides 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.

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

Item 2 – after subsection 6(4)

Item 2 of Schedule 1 inserts a new subsection 6(5) into the Principles. Subsection 6(5) provides that for section 6, an application is a ‘renewal application’ if an approved collection

centre was conducted on the premises within the two months before the application was made:

- (a) by the same approved pathology authority making the current application; or
- (b) by a different approved pathology authority than the authority making the application, and:
 - (i) the approved pathology authority previously operating the collection centre has ceased to be an approved pathology authority; or
 - (ii) the new application is being made as a result of the acquisition of interests in or merger activity involving the approved pathology authority that previously operated the collection centre.

Schedule 2 – Application

Item 1 - Application

Item 1 of Schedule 2 provides that the amendments made by items 1 and 2 of Schedule 1 only apply to applications for approval made after those items take effect. 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 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 2016

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 2016* (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 all approvals to be granted for a period of one year. As a result of the changes made by the Amendment Principles, collection centre approvals will be granted for a period of one year:

- (a) where the approval is a renewal of an approval for an ACC being operated on the same premises by the same approved pathology authority; or
- (b) where the application has been made by a different approved pathology authority than that which previously operated the ACC on the premises and the previous approved pathology authority has ceased to be an approved pathology authority entirely, or the previous authority has been involved in a merger or acquisition, resulting in the need for the new application.

Collection centre approvals will be granted for a period of six months in all other circumstances.

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

Human rights implications

The Regulations engage Articles 9 and 12 of the International Covenant on Economic Social and Cultural Rights (ICESCR), specifically the rights to health and social security.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The UN Committee on Economic Social and Cultural Rights (the Committee) has stated that the right to health is not a right for each

individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

Analysis

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 tax payable on the grant of a six month collection centre approval is reduced proportionally, meaning that applicants for new collection centres are not financially disadvantaged.

The duration of approvals for new ACC's is being shortened to six months as an interim measure prior to implementation of proposed changes to the ACC approval regime aimed at better enforcing compliance with the prohibited practices provisions of the Act in relation to certain payments for ACCs. This will ensure that any new ACC established during this period will be subject to the new arrangements within six months.

The changes made by the Amendment Principles do not affect human rights 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 has a positive effect on human rights issues.

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