

## EXPLANATORY STATEMENT

Issued by the Authority of the Minister for Health  
*Health Insurance Act 1973*

*Health Insurance (Eligible Collection Centres) Approval Amendment (Application Form) 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 (Application Form) Principles 2018* (the Amendment Principles) is to amend the Principles to ensure that applications received by the Minister for consideration and a decision on approval, are complete.

The amendment is administrative in nature. It is designed to ensure that the level of information presently collected through the application process is not adversely impacted by the Department's move to a more proactive approach to enforcement of the prohibited practices provisions of the *Health Insurance Act 1973* (Cth) with respect to ACC rents.

While most of the information supplied by applicants through the application process is required for consideration of and a decision on an application for approval, some of that information also informs the Department's understanding of rents (and other benefits) paid for premises. Without amendment, applicants could substantially impede the Department's ability to implement a more proactive approach by reducing the amount of information supplied.

The Amendment Principles provide that an application will be complete where the applicant has provided:

- a response to each question asked in the prescribed form;
- any information reasonably necessary to substantiate or explain each such response; and
- any additional information required by the Minister under subsection 5(3) of the Approval Principles.

The amendments made by the Amendment Principles will not apply to approvals which are in force at the commencement date. They will however apply to applications for approval or renewal made after that date. 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.

## **Consultation**

The change is administrative in nature and forms part of a broader strategy for strengthening enforcement by the Department of legislative requirements relating to pathology ACCs, consistent with the 2017-18 Budget measure: Pathology Approved Collection Centres – Enhanced Compliance. It is intended to ensure that the collection of information (which occurs presently) is not impacted by the move to more proactive enforcement of the prohibited practices provisions.

The Department has consulted extensively with the Pathology and General Practitioner (GP) sectors.

At its November 2017 roundtable with the Pathology and GP sectors, the Department advised that it would be updating the ACC approval application form to make all fields mandatory from 1 July 2018, giving effect the amendments in the Principles. There was no objection to these proposals.

As the changes implemented by the Principles are relatively minor and administrative in nature and key stakeholders were informed of their effects at the roundtable, further consultation regarding the Principles was not considered necessary.

Details of the Amendment Principles are set out in the [Attachment](#).

The Amendment Principles commence on the day after it is registered on the Federal Register of Legislation.

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*

**Details of the *Health Insurance (Eligible Collection Centres) Approval Amendment (Application Form) Principles 2018***

Section 1 – Name

Section 1 provides for the Principles to be referred to as the *Health Insurance (Eligible Collection Centres) Approval Amendment (Application Form) Principles 2018* **(the Amendment Principles)**.

Section 2 – Commencement

Section 2 provides that the Amendment Principles commence on the day after registration.

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 5(1)*

Item 1 of Schedule 1 provides for the repeal of subsection 5(1) of the Principles and its replacement with new subsections 5(1) and 5(1A).

Subsection 5(1) 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 5(1) provides that an application for approval of an eligible collection centre must not be considered by the Minister unless:

- (a) it is made:
  - (i) by an APA who is an eligible applicant; and
  - (ii) in writing and in the prescribed form; and
- (b) the application is complete.

New subsection 5(1A) provides that an application for approval of an eligible collection centre will be complete for the purposes of paragraph 5(1)(b) where the applicant has provided:

- (a) a response to each question asked in the prescribed form;

- (b) any information reasonably necessary to substantiate or explain each such response; and
- (c) any additional information required by the Minister under subsection 5(3).

A note to subsection 5(1A) notes that the prescribed form is available from the Department of Human Services. This previously formed a note to subsection 5(1), and has been updated to refer to the Department of Human Services.

## Schedule 2 – Application

### *Item 1 - Application*

Item 1 of Schedule 2 provides that the amendments made by items 1 of Schedule 1 only apply to applications for approval made after those items take effect. This will include applications for approval which are renewal applications within the meaning of subsection 6(5) of the Principles.

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. An application lodged electronically is taken to be made at the time the applicant uploads the prescribed form through the Department of Human Services' Health Professional Online Services (HPOS) portal.

## **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 (Application Form) 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 (Application Form) Principles 2018* (the Amendment Principles) amend the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* (the Principles) to provide that an application for approval of an eligible collection centre must not be considered by the Minister unless it is complete. The amendment is required to discourage applicants from submitting applications which are incomplete, contain partial information or do not include additional information required by the Minister to decide on an application under subsection 5(3).

The Minister may, under subsection 23DNBA(1) of the *Health Insurance Act 1973* (the Act), grant approval to an approved pathology authority for an eligible collection centre, where certain requirements in relation to the premises from which the proposed collection centre is to be conducted are satisfied.

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. Subsection 5(1) of the Principles previously provided that an application for approval of an eligible collection centre must not be considered by the Minister unless made by an APA who is an eligible applicant, and made in writing and in the prescribed form.

As a result of the changes made by the Amendment Principles, the applications that may be considered by the Minister will be reduced to the subset of those applications that are complete.

Subsection 5(1A) provides that an application will be complete where the applicant has provided:

- a response to each question asked in the prescribed form;
- any information reasonably necessary to substantiate or explain each such response; and
- any additional information required by the Minister under subsection 5(3).

The changes made by the Amendment Principles will only apply in respect of applications (including renewal applications) made after the amendment take effect.

## **Human rights implications**

The Principles as a whole 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.

The Amendment Principles Instrument is compatible with the right to health and right to social security as it implements the transparent approval of pathology specimen collection centres that provide scientifically and medically appropriate diagnostic services that are accessible by the public.

### 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. As a practical matter, they will require applicants to take steps to ensure that applicants are complete and are not submitted incomplete or with partial information. They require applicants to respond to all questions asked in the prescribed form and require applicants to provide any information reasonably necessary to substantiate or explain their responses. They will also require the applicant supply the additional information required by the Minister to decide on the application.

The changes made by the Amendment Principles do not affect the overall objective of providing appropriately approved pathology specimen collection centres through a transparent application process.

## **Conclusion**

This Legislative Instrument is compatible with human rights as it maintains the overall objective of promoting human rights, in particular, the right to health and the right to social security.

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