

## EXPLANATORY STATEMENT

### *Health Insurance Act 1973*

#### *Health Insurance (Approvals for Eligible Collection Centres) Principles 2020*

#### **Authority**

Subsection 23DNBA(4) of the *Health Insurance Act 1973* (the Act) requires the Minister to determine 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 pathology services rendered, pathology specimens must be collected at an approved eligible collection centre (ACC), or in other specified circumstances. The arrangements for ACCs are set out in the *Health Insurance (Approvals for Eligible Collection Centres) Principles 2020* (the Principles).

Subsection 33(3) of the *Acts Interpretation Act 1901*, provides that where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

#### **Purpose**

The *Health Insurance (Eligible Collections Centres) Approval Principles 2020* (the Principles) prescribe the prerequisites for the granting of approvals for ACCs, notice requirements and the duration of approval.

#### **Background**

The Principles repeal and remake the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* (previous Principles), due to sunset on 1 October 2020.

Medicare benefit is payable for a pathology service only where the pathology specimen is collected from the patient at a type of locations specified in subsection 16A(5AA) of the Act. One of these locations is an ‘approved collection centre’, being a specimen collection centre approved by the Minister under section 23DNBA of the Act.

Under section 23DNBA of the Act, the Minister may grant an approval to an Approved Pathology Authority (APA) to operate an ‘eligible collection centre’ on premises owned, leased or otherwise occupied by the APA. An eligible collection centre is a collection centre on premises owned, leased or sub-leased by an APA that is also the sole proprietor of at least one eligible pathology laboratory.

The Principles do not change the operation of the Instrument. As part of the review, there have some administrative amendments to the granting approvals process for eligible collection centres and transition provision for clarification purposes and updates to the definitions to ensure consistency in terminology reflected in the *Health Insurance Act 1973* and to update references legislation regulating the provision of pathology services. The Principles make no changes to the operation of matters such as requirements for an application or prerequisites to be considered an eligible collection centre or duration of approval.

As part of National Pathology Accreditation Program, all Approved Pathology Collection Centres must meet the accreditation standard titled *Guidelines for Approved Pathology Collection Centres (Requirements for Medical Pathology Specimen Collection)*. The

accreditation standard is amongst the suite of accreditation materials referenced in the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2017* that are in force from

time to time and are available from

<https://www1.health.gov.au/internet/main/publishing.nsf/Content/health-npaac-publication.htm>

## **Consultation**

Services Australia, which shares the responsibility for administering the application process for Approved Pathology Collection Centres with the Department of Health, has been consulted on the review of the Principles. Key pathology professional and representative stakeholder organisations have been advised of the sunseting legislative instrument, and provided the opportunity to provide any comments. No feedback was provided.

The Office of Best Practice Regulation has confirmed that given the instrument has been operating effectively and has been remade without any materially significant changes, a Regulation Impact Statement is not required nor a sunseting letter for the remaking of this Instrument (OPBR ID 43051).

The Principles commence on 1 October 2020.

Details of the Principles are set out in Attachment A.

The Principles is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

## **Details of the *Health Insurance (Approvals for Eligible Collection Centres) Principles 2020***

### **Section 1 Name**

This section provides that the name of this instrument is the *Health Insurance (Approvals for Eligible Collection Centres) Principles 2020*.

### **Section 2 Commencement**

This section provides that this instrument commences on 1 October 2020.

### **Section 3 Authority**

This section provides that this instrument is made under subsection 23DNBA(4) of the *Health Insurance Act 1973*.

### **Section 4 Schedules**

This section provides that the instrument specified in the Schedule to this instrument is repealed.

### **Section 5 Definitions**

This section defines key terms used in the instrument. Unless otherwise defined they have the same meaning as in the *Health Insurance Act 1973*. This incorporation is permitted by section 14 of the *Legislation Act 2003*, and that the provisions of the Act are incorporated as in force from time to time.

### **Section 6 Prerequisites**

This section provides the requirements that the eligible specimen collection centre must meet before an application for approval of an eligible collection centre can be approved by the Minister.

### **Section 7 Applicant**

This section provides criteria for Authorised Pathology Authorities (APA's) making an application for an eligible collection centre approval.

### **Section 8 Form and content of application**

This section sets out the requirements of the form and content that an application in order to be considered for approval to the Minister.

Acceptance by the Minister of the impracticality of compliance with some or all provisions of the Collection Centre Guidelines in particular circumstances, as envisaged in subparagraph 8(2)(d)(i) of the instrument is intended to be an administrative action that is not dependent on the instrument. The Principles refer to the acceptance (in describing the content of an undertaking that an applicant has power to give apart from the Principles), and are not the source of the Minister's power to accept the impracticability of compliance.

### **Section 9 Requirements for premises**

This section provides the requirements for an eligible collection premises, including premises equipment and staff training and employment status.

## **Section 10 Giving notice to applicant**

This section provides the requirements for notification of a decision by the Minister to grant approval or not to grant approval for an eligible collection centre. Applicants can seek the Minister's reconsideration of a decision.

## **Section 11 Duration of approval**

This section provides for the duration and commencement date of an approval once granted.

## **Section 12 Continuation of approvals**

This section provides transitional arrangements for any applications in the current form until such time a new form is approved.

## **Section 13 Continuation of form until new form approved**

This section outlines that the existing application form continues to apply until such time a new application form is approved.

## **Schedule 1 – Repeals**

### ***Health Insurance (Eligible Collection Centres) Approval Principles 2010***

#### **1 The whole of the instrument**

This Schedule repeals the *Health Insurance (Eligible Collection Centres) Approval Principles 2010*.

## **Statement of Compatibility with Human Rights**

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

### ***Health Insurance (Approvals for Eligible Collection Centres) Principles 2020***

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 Collections Centres) Approval Principles 2020* (the Principles) prescribe the prerequisites for the granting of approvals for Approved Collection Centres (ACC), notice requirements and the duration of approval.

Medicare benefit is payable for a pathology service only where the pathology specimen is collected from the patient at a type of locations specified in subsection 16A(5AA) of the Act. One of these locations is an ‘approved collection centre’, being a specimen collection centre approved by the Minister under section 23DNBA of the Act.

Under section 23DNBA of the Act, the Minister may grant an approval to an Approved Pathology Authority (APA) to operate an ‘eligible collection centre’ on premises owned, leased or otherwise occupied by the APA. An eligible collection centre is a collection centre on premises owned, leased or sub-leased by an APA that is also the sole proprietor of at least one eligible pathology laboratory.

The Principles repeal and remake the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* (previous Principles), due to sunset on 1 October 2020. The Principles do not change the operation of the Instrument. As part of the review, there have some administrative amendments to the granting approvals process for eligible collection centres and transition provision for clarification purposes and updates to the definitions to ensure consistency in terminology reflected in the *Health Insurance Act 1973* and to update references legislation regulating the provision of pathology services. The Principles make no changes to the operation of matters such as requirements for an application or prerequisites to be considered an eligible collection centre or duration of approval.

The Principles does not make any changes to the existing arrangements for the manner of applying for approval of a collection centre, or the operation of collection centres.

#### **Human rights implications**

The Principles does not engage any of the applicable rights or freedoms and do not impose any new requirements on APAs seeking approval of eligible collection centres. The effects of the Principles are limited to the business interests of persons granted an approval for an ACC.

Patient access to Medicare rebates for pathology services is not affected by the Principles.

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

#### **Conclusion**

This Legislative Instrument is compatible with the human rights as it does not engage any of the applicable rights or freedoms.

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