



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

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I, Paul McBride, as delegate of the Minister for Health, make the following principles.

Dated 14 September 2020

Paul McBride  
First Assistant Secretary  
Medical Benefits Division  
Department of Health

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# Contents

<b>Part 1—Preliminary</b>	1
1    Name.....	1
2    Commencement .....	1
3    Authority.....	1
4    Schedules .....	1
5    Definitions .....	1
<b>Part 2—Granting approvals for eligible collection centres</b>	3
<b>Division 1—Prerequisites for grant of approval</b>	3
<b>Subdivision A—General</b>	3
6    Prerequisites.....	3
<b>Subdivision B—Requirements for application</b>	3
7    Applicant.....	3
8    Form and content of application .....	3
<b>Subdivision C—Requirements for premises where centre is conducted</b>	4
9    Requirements for premises.....	4
<b>Division 2—Notice of decision on granting of approval</b>	5
10    Giving notice to applicant.....	5
<b>Division 3—Duration of approval</b>	6
11    Duration of approval .....	6
<b>Part 3—Application, saving and transitional provisions</b>	7
<b>Division 1—Provisions for this instrument as originally made</b>	7
12    Continuation of approvals.....	7
13    Continuation of form until new form approved .....	7
<b>Schedule 1—Repeals</b>	8
<i>Health Insurance (Eligible Collection Centres) Approval Principles 2010</i>	8



## Part 1—Preliminary

### 1 Name

This instrument is the *Health Insurance (Approvals for Eligible Collection Centres) Principles 2020*.

### 2 Commencement

- (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	Column 2	Column 3
Provisions	Commencement	Date/Details
1. The whole of this instrument	1 October 2020.	1 October 2020

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

- (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

### 3 Authority

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

### 4 Schedules

Each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

### 5 Definitions

Note: A number of expressions used in this instrument are defined in the Act, including the following:

- (a) accredited pathology laboratory;
- (b) approved pathology authority.

In this instrument:

*Act* means the *Health Insurance Act 1973*.

*APA* means approved pathology authority.

Section 5

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**approval**, for an eligible collection centre, has the meaning given by subsection 23DA(1) of the Act.

**category G pathology laboratory** means an accredited pathology laboratory the premises of which are approved under section 23DN of the Act as a category GX or category GY accredited pathology laboratory.

**category S pathology laboratory** means an accredited pathology laboratory the premises of which are approved under section 23DN of the Act as a category S accredited pathology laboratory.

**Collection Centre Guidelines** has the meaning given by subsection 23DA(1) of the Act.

**eligible collection centre** has the meaning given by subsection 23DA(1) of the Act.

## **Part 2—Granting approvals for eligible collection centres**

### **Division 1—Prerequisites for grant of approval**

#### **Subdivision A—General**

##### **6 Prerequisites**

The Minister must not grant an approval for an eligible collection centre unless:

- (a) an application for the approval has been made and meets the requirements of Subdivision B; and
- (b) the requirements of Subdivision C are met for the premises on which the eligible collection centre is, or is to be, conducted.

#### **Subdivision B—Requirements for application**

##### **7 Applicant**

- (1) The application must be made by an APA who is covered by one of subsections (2), (3) and (4).

*Operator and proprietor of category G pathology laboratory*

- (2) This subsection covers an APA who operates, and is the proprietor of, an accredited pathology laboratory that is a category G pathology laboratory.

*APA with arrangement for use of category G pathology laboratory*

- (3) This subsection covers an APA who:
  - (a) has entered into an arrangement with another APA for the use of an accredited pathology laboratory that is a category G pathology laboratory; and
  - (b) before the commencement of this instrument, had an approval for an eligible collection centre granted in accordance with the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* because the APA was an eligible applicant because of paragraph 5(2)(b) of that instrument.

*Operator and proprietor of category S pathology laboratory*

- (4) This subsection covers an APA who operates, and is the proprietor of, an accredited pathology laboratory that is a category S pathology laboratory that is proposing to collect only specimens for the kind of pathology services in respect of which the premises of the laboratory are approved under section 23DN of the Act.

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

- (1) The application must be in writing and in a form approved by the Minister.
- (2) The application must include:

**Section 9**

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- (a) a response to each question in the approved form; and
- (b) information (if any) that is reasonably necessary to substantiate or explain each response; and
- (c) additional information (if any) that is required by the Minister to be provided at the time of lodgement of the application to allow the application to be decided; and
- (d) a written undertaking that the applicant:
  - (i) will comply with the Collection Centre Guidelines in operating the eligible collection centre while the approval is in force, except so far as the Minister accepts that compliance with some, or all, provisions of the Guidelines is not reasonably practicable in particular circumstances; and
  - (ii) will, within 24 hours after a failure to comply with the Collection Centre Guidelines in operating the eligible collection centre while the approval is in force, give the Chief Executive Medicare written notice of the failure and the reason for the failure.

**Subdivision C—Requirements for premises where centre is conducted**

**9 Requirements for premises**

- (1) This section applies to the premises where the eligible collection centre is, or is to be, conducted.
- (2) On the premises there must be the equipment necessary for the collection and preparation of specimens for pathology procedures.
- (3) The staff at the premises must:
  - (a) include persons trained in procedures for the collection and preparation of pathology specimens; and
  - (b) be persons who are either:
    - (i) employed by the APA who has made the application for the approval; or
    - (ii) engaged directly or indirectly by the APA under a contract that gives the APA power to generally direct or control the work of the persons on the premises.



## **Division 2—Notice of decision on granting of approval**

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

The Minister must give an APA who applies for approval for an eligible collection centre written notice of:

- (a) the decision to grant or not grant the approval; and
- (b) if the decision is to not grant the approval—the applicant’s right under subsection 23DO(2DA) of the Act to apply to the Minister for reconsideration of the decision.

## **Division 3—Duration of approval**

### **11 Duration of approval**

- (1) An approval for an eligible collection centre has effect for 2 years starting on the day it comes into force, subject to:
  - (a) section 23DNG of the Act (revocation of approval on the Minister's initiative); and
  - (b) section 23DNH of the Act (cancellation of approval on request).
- (2) An approval for an eligible collection centre comes into force:
  - (a) on the day it is granted; or
  - (b) on the day specified in the notice of the approval, which must not be a day before the approval was granted, unless the Minister is satisfied that special circumstances justify specifying an earlier day.

## **Part 3—Application, saving and transitional provisions**

### **Division 1—Provisions for this instrument as originally made**

#### **12 Continuation of approvals**

To avoid doubt, the repeal of the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* by this instrument does not affect the period for which an approval for an eligible collection centre granted before that repeal is in force.

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

- (1) This section has effect for the purposes of subsection 8(1) and applications made before the Minister approves a form for the purposes of that subsection.
- (2) The form that was prescribed by the Minister for the purposes of the *Health Insurance (Eligible Collection Centres) Approval Principles 2010* immediately before 1 October 2020 has effect as if it were approved by the Minister for the purposes of subsection 8(1) of this instrument.
- (3) The form has effect as if:
  - (a) the first declaration in section 30 of the form were an undertaking described in subparagraph 8(2)(d)(i) of this instrument; and
  - (b) the first and second understandings in section 30 of the form were an undertaking described in subparagraph 8(2)(d)(ii) of this instrument.

## **Schedule 1—Repeals**

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

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

Repeal the instrument.