



## **Health Insurance (Approved Pathology Undertakings) Approval 2017**

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I, GREG HUNT, Minister for Health, make the following approval under subsection 23DB(1) of the *Health Insurance Act 1973*.

Dated 25 September 2017

Greg Hunt  
Minister for Health

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## **1 Name**

This is the *Health Insurance (Approved Pathology Undertakings) Approval 2017*.

## **2 Commencement**

This instrument commences on the day after it is registered.

## **3 Authority**

This instrument is made under subsection 23DB(1) of the *Health Insurance Act 1973*.

## **4 Definitions**

Words in this instrument have, unless they are otherwise defined, the same meaning as in the *Health Insurance Act 1973*.

## **5 Revocations**

All previous approvals made under subsection 23DB(1) of the *Health Insurance Act 1973* are revoked.

## **6 Approval of forms of undertaking**

*Approved form—approved pathology practitioners*

- (1) The form contained in Schedule 1 is the approved form of undertaking to be given by persons who wish to become approved pathology practitioners for the purposes of subsection 23DB(1) of the *Health Insurance Act 1973*.

*Approved form—approved pathology authorities*

- (2) The form contained in Schedule 2 is the approved form of undertaking to be given by persons who wish to become approved pathology authorities for the purposes of subsection 23DB(1) of the *Health Insurance Act 1973*.

# Schedule 1—Approved Pathology Practitioner Undertaking

Note: The form contained in this Schedule is the approved form of undertaking to be given by persons who wish to become approved pathology practitioners for the purposes of subsection 23DB(1) of the *Health Insurance Act 1973*

## Part 1—Undertaking

### 1 Interpretation

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

- (a) accredited pathology laboratory
- (b) approved pathology authority
- (c) approved pathology practitioner
- (d) medical practitioner
- (e) participating midwife
- (f) participating nurse practitioner
- (g) pathology service
- (h) relevant civil contravention
- (i) relevant offence
- (j) relevant person
- (k) treating practitioner

(1) In this undertaking:

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

*APA* means an approved pathology authority.

*APP* means an approved pathology practitioner.

*APL* means an accredited pathology laboratory.

*account* means an itemised list of pathology services rendered that may be eligible for payment under Medicare including a claim for assigned benefits pursuant to the Act.

*Assistant Secretary in the Provider Benefits Integrity Division of the Department of Health* means any person from time to time holding, acting in, or performing the duties of the position titled Assistant Secretary in the Provider Benefits Integrity Division within the Department of Health.

*Chief Executive Medicare* means the person for the time being holding the position titled Chief Executive Medicare in the *Human Services (Medicare) Act 1973* and includes an officer holding a valid delegation to make a particular decision in place of the Chief Executive Medicare.

*Department of Human Services* means the Department administered by the Minister who administers the *Human Services (Centrelink) Act 1997*.

*Director, Medicare Provider Eligibility and Accreditation* means the person from time to time holding, acting in, or performing the duties of the position titled Director, Medicare Provider Eligibility and Accreditation within the Department of Human Services.

*independent body* has the same meaning as in the *Health Insurance (Accredited Laboratories—Approval) Principles 2017*, or any legislation made in substitution for those Principles.

**laboratory** means accredited pathology laboratory, given approval under section 23DN of the Act.

**Minister** means the Minister of the Commonwealth for the time being administering the Act and includes an officer holding a valid delegation to make a particular decision in place of the Minister.

**quality assurance program** means a program offered for the purpose of testing proficiency in the testing of pathology specimens.

**scientist** means a person who possesses one of the following qualifications:

- (a) a degree in science or applied science with subjects relevant to the field of pathology awarded after not less than three years full-time study, or an equivalent period of part-time study, at a university in Australia, that provides for direct entry or following examination to a professional class of membership of the Australasian Association of Clinical Biochemists, Australian Institute of Medical Scientists, Australian Society for Microbiology, Australian Society of Cytology, Human Genetics Society of Australasia;
- (b) an associate qualification conferred by the Australian Institute of Medical Technologists before 1 December 1973.

**service** means:

- (a) pathology service as defined under the Act; and
- (b) a health service as defined under section 3C of the Act which under that section is to be treated as if there were an item in the pathology services table which related to it.

**State accredited laboratory** means:

- (a) a pathology laboratory which is accredited pursuant to State legislation; and
- (b) in relation to a laboratory which is situated in Victoria—an accredited pathology laboratory under the *Pathology Services Accreditation Act 1984* of Victoria.

**workday** means, in respect of a laboratory, a calendar day during which the laboratory provides pathology services.

- (2) A reference in this undertaking to writing, documents and records includes material in electronic form where recorded and submitted in accordance with the Information Technology Standard *Notice of Information Technology (IT) Requirements under the Electronic Transactions Act 1999 for Public Key Technology (PKI)*, dated 1 September 2009, made by Medicare Australia, as in force on that date.

*Note:* the Information Technology Standard is available from the Department of Human Services at: <https://www.humanservices.gov.au/organisations/health-professionals/services/medicare/public-key-infrastructure>

## 2 Compliance with legislation

- (1) I have familiarised myself with the operation of the legislation listed in Part 2 of this Schedule.
- (2) I undertake to comply with the legislation listed in Part 2 of this Schedule, as in force from time to time, or any legislation made in substitution for that legislation.
- (3) I undertake not to take any action that would constitute a relevant offence or relevant civil contravention as defined in subsection 124B(1) of the Act.

- (4) I acknowledge that a failure to comply with the requirements of subsection (2) or (3) constitutes a breach of this undertaking whether or not that failure has been, or is likely to be, proven in court proceedings.
- (5) I am aware that if the Minister grants the application in support of which this undertaking is given the undertaking may outlast the period for which the Minister's approval is given.

### 3 Personal supervision

- (1) I acknowledge that it is my obligation, subject to subsections (3) and (4), personally to supervise any person who renders any service on my behalf and I undertake to accept person responsibility for the rendering of that service under the following conditions of personal supervision:
  - (a) subject to the following conditions, I will usually be physically available in the laboratory while services are being rendered at the laboratory;
  - (b) I may, subject to paragraph (f) below, be physically absent from the laboratory while services are being rendered outside its normal hours of operation but in that event I will leave with the person rendering the service particulars of the manner in which I may be contacted while the service is being rendered and I must be able to personally attend at the laboratory while the service is being rendered or formally designate another APP present while I am absent;
  - (c) I may, subject to paragraph (f) below, be absent from the laboratory for brief periods due to illness or other personal necessity, or to take part in activities which, in accordance with normal and accepted practice, relate to the provision of services by that laboratory;
  - (d) I will personally keep a written log of my absences from the laboratory that extend beyond one workday in respect of that laboratory and will retain that log in the laboratory for 18 months from date of last entry;
  - (e) if I am to be absent from the laboratory for more than 7 consecutive workdays, I will arrange for another APP to personally supervise the rendering of services in the laboratory. That arrangement shall be recorded in writing and retained in the laboratory for 18 months from date of last entry. Until such person is appointed, and his or her appointment is recorded in writing, I will remain personally responsible to comply with this undertaking;
  - (f) if a service is being rendered on my behalf by a person who is not:
    - (i) a medical practitioner; or
    - (ii) a scientist, or
    - (iii) a person having special qualifications or skills relevant to the service being rendered;and no person in the above groups is physically present in the laboratory, then I must be physically present in the laboratory and closely supervise the rendering of the service;
  - (g) I accept responsibility for taking all reasonable steps to ensure that in regard to services rendered by me or on my behalf:
    - (i) all persons who render services are adequately trained; and
    - (ii) all services which are to be rendered in the laboratory are allocated to persons employed by the APA and, these persons shall have appropriate qualifications and experience to render the services; and
    - (iii) the methods and procedures in operation in the laboratory for the purpose of rendering services are in accordance with proper and correct practices; and
    - (iv) for services rendered, proper quality control methods are established and reviewed to ensure their reliability and effectiveness; and

- (v) results of services and tests rendered are accurately recorded and sent to the treating practitioner and, where applicable, a referring practitioner;
  - (h) if I render, or there is rendered on my behalf, a service which consists of the analysis of a specimen which I know, or have reason to believe, has been taken other than in accordance with the provisions of section 16A(5AA) of the Act I will endorse, or cause to be endorsed, on the assignment form or the account for that service, as the case may be, particulars of the circumstances in which I believe, or have reason to believe, the specimen was taken.
- (2) Where services are to be rendered on my behalf in a Category B laboratory as defined in the *Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017*, I undertake to take all reasonable measures to ensure that the service is rendered under the supervision of an appropriate person as required by those Principles.
  - (3) I acknowledge that any act or omission by a person acting with my express or implied authority that would, had it been done by me, have resulted in a breach of this undertaking, constitutes a breach of this undertaking by me.
  - (4) Paragraphs (1)(a) – (f) and subsection (2) do not apply where a laboratory is limited to services (and associated equipment for those services) as detailed in Part 4 of this Schedule.

#### **4 Dealings with relevant person**

- (1) I undertake to inform the Director, Medicare Provider Eligibility and Accreditation if, to my knowledge, any of the following occur:
  - (a) I become a relevant person;
  - (b) I become in control of operations of a relevant person;
  - (c) any person who derives, or can reasonably be expected to derive (whether directly or indirectly) financial benefit from the services I render within a laboratory becomes a relevant person;
  - (d) I become financially associated with a relevant person;
  - (e) I am required to appear before the state or territory body which has jurisdiction to affect my registration as a medical practitioner for misconduct or unprofessional conduct.
- (2) I undertake not to employ or enter into a contract or understanding with a person who is, to my knowledge, a relevant person.

#### **5 Information to be accurate**

- (1) I undertake to ensure that information provided to the Department of Human Services for services rendered by me or on my behalf, including information relating to claims for payment, is accurate and complete.
- (2) If I become aware that information which has been provided to the Department of Human Services is or becomes inaccurate or incomplete, I undertake to provide the Department with such further information as will correct the earlier information as soon as possible.
- (3) If information provided to the Department of Human Services is inaccurate or incomplete I undertake to provide the Department with such further information as it requests. The information will be provided in such reasonable form as the Department requires.



- (4) I undertake to advise the Director, Medicare Provider Eligibility and Accreditation in writing of any change in information already provided for the purpose of approval as a pathology practitioner.

## **6 Quality assurance**

- (1) On request of an independent body, I undertake to provide the independent body with copies of all quality assurance program reports and related information relating to the conduct of my activities as an APP.
- (2) Where I participate in a quality assurance program for the purpose of proficiency testing, I undertake to authorise the provider of any such quality assurance program to release reports and information generated as part of the quality assurance program to an independent body.
- (3) I undertake to take reasonable steps to obtain any necessary consents to enable me to provide reports or information to the independent body in accordance with subsection (1).
- (4) Nothing in this section obliges me to provide reports or information to the independent body, or to authorise any other person to do so, in contravention of any law.

## **7 Request and use of information**

- (1) If:
  - (a) the Director, Medicare Provider Eligibility and Accreditation; or
  - (b) an Assistant Secretary in the Provider Benefits Integrity Division of the Department of Health;

makes a written request, I undertake to provide any relevant information specified in the request relating to services provided by or on my behalf, including any matter arising out of this undertaking.

- (2) I acknowledge that information provided pursuant to this undertaking may be copied, disseminated or otherwise made available to any of the following:
  - (a) the independent body;
  - (b) officers of the Department of Health;
  - (c) persons performing the duties of an officer of the Department of Health;
  - (d) the Chief Executive Medicare;
  - (e) Departmental employees as defined in the *Human Services (Medicare) Act 1973*.

## **8 Notice to practitioners, patients or other persons**

- (1) I undertake to notify in writing any practitioner, participating nurse practitioners, participating midwives, patient or other person requesting or relying on services rendered by me or on my behalf if approval to render those services has been revoked, varied or refused by the Minister.
- (2) A notice under subsection (1) shall be restricted to services rendered to practitioners, participating nurse practitioners, participating midwives, patients or other persons who, according to a report of the independent body, may have received inaccurate or otherwise unreliable reports.
- (3) I undertake to provide a notice pursuant to subsection (1) within 5 working days of being notified that my approval to render services have been revoked, varied or refused.

- (4) In the event that I am unable to comply with subsection (1), I undertake to provide such assistance as requested by the Director, Medicare Provider Eligibility and Accreditation that will enable such a notice to be given on my behalf.

## **9 Agreements, arrangements and contracts of employment with Approved Pathology Authority**

- (1) I undertake not to render any service in a laboratory in the absence of an agreement, arrangement or contract of employment between the laboratory proprietor and me.
- (2) I undertake to ensure that any contract of employment or other agreement or arrangement between myself and an Authority and any amendment or variation thereto, is in writing signed by all the parties and does not, in any way, control me in the discharge of my responsibilities as set out in this undertaking.

## **10 Accounts for services rendered by employed APP**

Where a service has been rendered by or on my behalf, I undertake to ensure that an account for that service is raised on my behalf by the APA, being the proprietor of the laboratory in which the service was rendered and that, no further account will be raised by me. I undertake to ensure that such account includes, and is supported by, information and particulars required by the Act.

## **11 No inducement to use services**

- (1) I undertake not to accept a request for services by me or on my behalf where any benefit or incentive (other than an item set out in Part 3 of this Schedule) has been directly or indirectly offered or supplied to the requesting practitioner or employer of that practitioner by the APA with which I have an agreement, arrangement or contract of employment.
- (2) The obligation under subsection (1) only arises where I ought reasonably to have known that such benefit or incentive has been offered or supplied.

## **12 Time and method of complying with undertakings**

- (1) I undertake to comply with any obligation imposed by this undertaking within 14 days of the obligation arising, unless otherwise specified.
- (2) Any information I am required by this undertaking to provide to the Director, Medicare Provider Eligibility and Accreditation must be:

- (a) delivered or posted to

The Director, Medicare Provider Eligibility and Accreditation  
Department of Human Services  
PO Box 1001  
TUGGERANONG DC ACT 2901

Or another address specified by the Department by notice in writing to me; or

- (b) emailed to [co.gp.manager.pathology@humanservices.gov.au](mailto:co.gp.manager.pathology@humanservices.gov.au).

- (3) Any information provided under paragraph (2)(a) must be signed by me or by a person authorised in writing to sign on my behalf.

- (4) I undertake to take adequate steps to ensure that only authorised persons have access to my email system.
- (5) I acknowledge that section 163 of the *Evidence Act 1995* will apply to any document posted to me by the Department of Human Services at the address nominated in the application in support of which this undertaking is given or at such other address as may later be provided by me in writing to the Department of Human Services.

## **Part 2—Legislation**

*Health Insurance Act 1973*

*Health Insurance Regulations 1975*

*Human Services (Medicare) Act 1973*

*Human Services (Medicare) Regulations 2017*

*Health Insurance (Pathology) (Fees) Act 1991*

*Health Insurance (Approved Pathology Specimen Collection Centres) Tax Act 2000*

*Health Insurance (Pathology Services) Regulations 2015*

*Health Insurance (Pathology Services Table) Regulations 2017*

*Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017*

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

*Health Insurance (Pathologist-Determinable Services) Determination 2015*

*Health Insurance (Permitted Benefits-Pathology Services) Determination 2008*

*Health Insurance (Prescribed Pathology Services) Determination 2011*

*Health Insurance (Eligible Pathology Laboratories) Determination 2015*

## **Part 3—Items an Authority may provide requesting practitioners**

Note: In general, these are items which can only be used for the collection of specimens for pathology testing or, if other uses are possible, when supplied by APPs to referrers, will only be used for collection purposes. These are mostly single use items employed in the collection of pathology samples. These are the only items/services an APP/APA may supply free of charge, discounted or on a non-commercial basis, to a practitioner that requests or, intends to request, pathology services. There is no obligation for a pathologist to supply any of the accepted items to a requesting practitioner.

### **Blood collection**

- Needle Barrel Holders;
- Vacutainer (or equivalent) needles;
- Syringes 5mls or larger;
- Needles 21, 23 gauge;
- Alcowipes (or similar individual alcohol wipes);
- Spreaders for blood films;
- Small test tube racks;

### **Cervical cytology collection materials**

- Spray fixative;
- Cervix spatulas;
- Cyto brush;
- Direct to vial kits;
- Slides and slide carriers/holders;

## **Histology**

- Formalin or other fixative;
- Appropriate containers and media for specimens;
- Punch biopsy;

## **Microbiological specimens**

- All microbiological or virology swabs and transport media;
- Urine containers;
- Faeces containers;
- Paediatric urine collection kits;
- Chlamydia specific collection and transport receptacles;
- TB specific collection receptacles;
- Blood culture bottles;
- Petri dishes;
- Specimen biohazard bags/rubber bands;

## **Non cervical cytology**

Appropriate containers and media for urine, sputum and other body fluid cytology and cytology samples collected directly from tissues by the procedure of Fine Needle Aspiration Cytology (FNA);

## **Biochemistry**

- Timed urine (eg 24 hour) collection containers;
- Faecal fat collection containers;
- Glucose drink for GTT;
- Centrifuges, but to remain the property of APA, and only if practice demographics (in terms of time) from laboratory are such that failure to separate sera/plasma will damage specimen;

## **Stationery/Instruction Sheets**

- Paper or electronic request pads/forms/software;
- Medicare assignment forms DB3, including software facilitating electronic assignment;
- Repatriation assignment forms, including software facilitating electronic assignment;
- Telephone result pads;
- Stock request pads;
- Miscellaneous forms eg tube guides, practice information handbooks;
- All patient instruction sheets/education material;

## **Other**

- Fridge, where refrigeration is vital for the preservation of specimens (ie Laboratory being a long distance from collection point). Fridge must be labelled with Pathology Company name, and used exclusively for pathology purposes;
- Insulated containers such as eskies for specimen transport (must be labelled as property of laboratory);
- Other specimen transport containers (must be labelled as property of laboratory);
- Specimen pick up receptacles (eg night boxes), must be labelled as property of laboratory;

- Pathology download software specifically to retrieve pathology results for the laboratory. Pathology download software which is part of a larger suite should not be provided – where additional functionality cannot be separated from the software, a written licence agreement at normal commercial rates must exist between the APA and requesting practitioner or, agreement must be established in writing prohibiting use of non-pathology software reporting components.
- Disposable vaginal speculums

## **Part 4—Laboratory Services**

Note: Paragraphs 3(1)(a) to (f) and subsection 3(2) of Part 1 of this Schedule do not apply where a laboratory is limited to services (and associated equipment for those services) as detailed in this Part. These services will be updated from time to time in consultation with the Royal College of Pathologists Australasia.

- Blood gas analysis
- Haemoglobin Ometer
- Glucose Reading

## Part 5—Execution of undertaking

I \_\_\_\_\_  
(full name in block letters)

a medical practitioner who is or wishes to become an approved pathology practitioner, hereby give the undertaking recorded in this Schedule. I acknowledge that a breach of this undertaking may be referred to a Medicare Participation Review Committee (MPRC) in accordance with the Act and, pursuant to section 124FB of the Act, the MPRC may make a number of determinations including that Medicare benefits should not be payable for up to 5 years.

I request the Minister or a delegate of the Minister to accept the undertaking under section 23DC of the Act. I certify that all information in this application is true and correct.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Address:

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Witness (see 'Applicant Instructions' for detail on witness requirements & execution of undertaking)

I, \_\_\_\_\_, hereby assert that the applicant is known to me or, if not known, am satisfied as to her/his identity, and did witness the signing of this instrument before me on this day.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Address:

# Schedule 2 —Approved Pathology Authority Undertaking

Note: The form contained in this Schedule is the approved form of undertaking to be given by persons who wish to become approved pathology authorities for the purposes of subsection 23DB(1) of the *Health Insurance Act 1973*

## Part 1—Undertaking

### 1 Interpretation

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

- (a) accredited pathology laboratory
- (b) approved collection centre
- (c) approved pathology authority
- (d) approved pathology practitioner
- (e) medical practitioner
- (f) participating midwife
- (g) participating nurse practitioner
- (h) pathology service
- (i) relevant offence
- (j) relevant person

(1) In this undertaking:

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

*ACC* means an approved collection centre.

*APA* means an approved pathology authority.

*APP* means an approved pathology practitioner.

*APL* means an accredited pathology laboratory.

*account* means an itemised list of pathology services rendered for which Medicare benefits may be payable including a claim for assigned benefits pursuant to the Act.

*approved premises* means any premises approved under section 23DN (a laboratory) or section 23DNBA (a collection centre) of the Act.

*Assistant Secretary in the Provider Benefits Integrity Division of the Department of Health* means any person from time to time holding, acting in, or performing the duties of the position titled Assistant Secretary in the Provider Benefits Integrity Division within the Department of Health.

*Authority* means the person giving the undertaking for the purpose of approval as an APA under section 23DF of the Act.

*Chief Executive Medicare* means the person for the time being holding the position titled Chief Executive Medicare in the *Human Services (Medicare) Act 1973* and includes an officer holding a valid delegation to make a particular decision in place of the Chief Executive Medicare.

*Department of Human Services* means the Department administered by the Minister who administers the *Human Services (Centrelink) Act 1997*.

*Director, Medicare Provider Eligibility and Accreditation* means the person from time to time holding, acting in, or performing the duties of the position titled Director,

Medicare Provider Eligibility and Accreditation within the Department of Human Services.

**entity** means a legal entity.

**independent body** has the same meaning as in the *Health Insurance (Accredited Laboratories—Approval) Principles 2017* or as in any instrument made in substitution for those Principles.

**laboratory** means accredited pathology laboratory, given approval under section 23DN of the Act.

**Minister** means the Minister of the Commonwealth for the time being administering the Act and includes an officer holding a valid delegation to make a particular decision in place of the Minister.

**occupier of premises** means:

- (a) the person in charge or control, or apparently in charge or control, of the premises; or
- (b) a person who represents or apparently represents that person.

**premises** means the premises of the Authority signing this undertaking and shall include laboratory premises, administrative premises, collection centre premises and any other place where the authority conducts business for the purpose of providing a pathology service pursuant to the Act.

**principal shareholder** means, in relation to a company, the ten persons or bodies holding the greatest number of shares.

**proprietor** means, in relation to premises, owner, lessee or other person having a right to possession.

**quality assurance program** means a program offered for the purpose of testing proficiency in the testing of pathology specimens.

**service** means:

- (a) pathology service as defined under the Act; and
- (b) a health service as defined under section 3C of the Act which under that section is to be treated as if there were an item in the pathology services table which related to it.

**scientist** means a person who possesses one of the following qualifications:

- (a) a degree in science or applied science with subjects relevant to the field of pathology awarded after not less than three years full-time study, or an equivalent period of part-time study, at a university in Australia, that provides for direct entry or following examination to a professional class of membership of the Australasian Association of Clinical Biochemists, Australian Institute of Medical Scientists, Australian Society for Microbiology, Australian Society of Cytology or Human Genetics Society of Australasia; or
- (b) an associate qualification conferred by the Australian Institute of Medical Technologists before 1 December 1973.

**senior scientist** means a scientist who has had not less than 10 years full-time relevant laboratory experience and who possesses one of the following qualifications:

- (a) a Doctorate of Philosophy in a subject relevant to the field of pathology; or
- (b) a Fellowship of the Australasian Association of Clinical Biochemists; or
- (c) a Fellowship of the Australian Institute of Medical Scientists; or



- (d) a Fellowship of the Australian Society for Microbiology (medical/clinical microbiology); or
- (e) a Fellowship of the Human Genetics Society of Australasia.

**State accredited laboratory** means:

- (a) a pathology laboratory which is accredited pursuant to state legislation; and
  - (b) in relation to a laboratory which is situated in Victoria – an accredited pathology laboratory under the *Pathology Services Accreditation Act 1984* of Victoria.
- (2) A reference in this undertaking to writing, documents and records includes material in electronic form where recorded and submitted in accordance with the Information Technology Standard *Notice of Information Technology (IT) Requirements under the Electronic Transactions Act 1999 for Public Key Technology (PKI)*, dated 1 September 2009, made by Medicare Australia, as in force on that date.

*Note:* the Information Technology Standard is available from the Department of Human Services at: <https://www.humanservices.gov.au/organisations/health-professionals/services/medicare/public-key-infrastructure>

## 2 Compliance with legislation

- (1) As an authorised representative of the Authority, I have familiarised myself with the operation of the provisions of the legislation listed in Part 2 of this Schedule.
- (2) The Authority undertakes to comply with the legislation listed in Part 2 of this Schedule, as in force from time to time, or any legislation made in substitution for that legislation.
- (3) The Authority undertakes not to take any action that would constitute a relevant offence as defined in subsection 124B(1) of the Act.
- (4) The Authority undertakes not to contravene Part IIBA of the Act, including but not limited to in relation to payments or other benefits offered, provided, asked for or received, in respect of an ACC for which the Authority has approval.
- (5) The Authority acknowledges that a failure to comply with the requirements of subsections (2), (3) or (4) constitutes a breach of this undertaking whether or not that failure has been, or is likely to be, proven in court proceedings.
- (6) I am aware that if the Minister grants the application in support of which this undertaking is given the undertaking may outlast the period for which the Minister's approval is given.

## 3 Persons Acting on behalf of the Authority

- (1) The Authority acknowledges that it is responsible and accountable for any breach of this undertaking by any person who, whether by contract of employment or otherwise, and in relation to a matter in relation to which this undertaking is given:
  - (a) acts on behalf of the Authority; or
  - (b) is in a position to influence or control the activities of the Authority; or
  - (c) to the knowledge of the Authority, holds themselves out to act on behalf of the Authority.

- (2) The Authority undertakes to ensure that any person described in subsection (1) is aware of this undertaking.
- (3) The Authority undertakes to remain accountable for any act by another APA, where such APA is a wholly owned subsidiary company or parent company of the Authority, that may result in a breach of the parent company or subsidiary company APA undertaking.

#### **4 Financial affairs**

- (1) The Authority undertakes to inform the Director, Medicare Provider Eligibility and Accreditation if any of the following occur:
  - (a) a matter relating to the financial affairs of the Authority is of such a nature that it has affected, or is likely to affect, the capability of the Authority to conduct the approved premises in the manner required by the legislation listed in Part 2 of this Schedule; or
  - (b) a qualified audit report has been made relating to the financial affairs of the Authority or its management of the approved premises.
- (2) Where the Authority provides the Director, Medicare Provider Eligibility and Accreditation with information referred to in subsection (1), the Authority undertakes to include with that information a statement setting out the steps that the Authority has undertaken or proposes to undertake to deal with the matters to which the information relates.
- (3) The Authority undertakes to inform the Director, Medicare Provider Eligibility and Accreditation if it is wound up or made bankrupt or if a trustee, liquidator, receiver, manager, administrator or court appointed agent is appointed to control the affairs of the Authority.

#### **5 Dealings with relevant person**

- (1) The Authority undertakes to inform the Director, Medicare Provider Eligibility and Accreditation if, to its knowledge:
  - (a) the Authority becomes a relevant person;
  - (b) the Authority obtains control of the operations of a relevant person;
  - (c) any person who derives, or can reasonably be expected to derive (whether directly or indirectly) financial benefit from the conduct by the Authority of business at the approved premises becomes a relevant person;
  - (d) the Authority comes to have a financial association with a relevant person;
  - (e) a director, secretary or officer of the Authority becomes a relevant person.
- (2) The Authority undertakes not to employ or enter into a contract or understanding with a relevant person.

#### **6 Information to be accurate**

- (1) The Authority undertakes to ensure that any information it provides to the Department of Human Services, including that relating to claims for payment is, accurate and complete.
- (2) The Authority undertakes to advise the Director, Medicare Provider Eligibility and Accreditation in writing within 14 days of any change in any of the particulars contained in applications provided for the purpose of approval as an APA, APL or ACC.

- (3) The Authority undertakes to inform the Department of Human Services in writing within 14 days should it become aware, or have reason to believe, that inaccurate or incomplete information has been provided to the Department.
- (4) The Authority undertakes to provide the Department of Human Services any information relating to the services provided by it, or any person on its behalf, including any matter arising out of this undertaking, requested by the Department in writing within 14 days of such request.

## **7 Inspection of Premises**

- (1) The Authority undertakes, at any reasonable time and with 12 hours notice, to permit a person or persons authorised in writing by the Director, Medicare Provider Eligibility and Accreditation to:
  - (a) enter and inspect the premises; and
  - (b) inspect any equipment used in relation to the rendering of services in the premises; and
  - (c) inspect any process in the rendering of services in the premises; and
  - (d) inspect documents and other records related to staffing, supervision, quality assurance programs and the rendering of services in the premises; and
  - (e) make and retain copies of, or take and retain extracts from, any such documents or records detailed at paragraph (d) with proper regard for individual patient confidentiality.
- (2) A time shall be deemed to be reasonable if it is between the hours of 9 am and 5 pm on a weekday or at another time when the premises are operating.
- (3) An inspection as described in subsection (1) may be undertaken without notice and at other times if the Minister or Chief Executive Medicare certifies in writing that the inspection is necessary in the interests of public safety.
- (4) The Authority is not required to permit an inspection as described in section 7(1) unless the person has made a copy of their authorisation available to the occupier of the premises. This provision does not apply to an inspection under section 7(3)
- (5) The powers conferred by this section are in addition to, and do not restrict, those conferred by section 23DNJ of the Act.

## **8 Cooperation with independent body**

- (1) The Authority undertakes, at a time and date agreed to by the Authority and independent body, to permit a person or persons authorised by an independent body to:
  - (a) enter and inspect the premises; and
  - (b) inspect any equipment used in relation to the rendering of services in the premises; and
  - (c) inspect any process in the rendering of services in the premises; and
  - (d) inspect documents and other records related to staffing, supervision, quality assurance programs and the rendering of services in the premises; and
  - (e) make and retain copies of, or take and retain extracts from, any such documents or records detailed at paragraph (d) with proper regard for individual patient confidentiality.
- (2) The Authority undertakes to provide to an independent body such information, including reports and information relating to quality assurance activities, as it reasonably requests.

- (3) The Authority is not required to permit an inspection as described in subsection (1) unless the person has made a copy of their authorisation available to the occupier of the premises.
- (4) If an independent body recommends that the Authority undertake any remedial activities as a result of an inspection, the Authority undertakes to use its best endeavours to comply with that recommendation within any time period stated by the independent body. The Authority also undertakes to inform the independent body of the action that has been taken to give effect to the recommendation.
- (5) If it becomes apparent to the Authority that it is not able to comply with a recommendation of the independent body referred to in subsection (4) or is not able to comply within the period recommended by the independent body, the Authority undertakes to advise the Director, Medicare Provider Eligibility and Accreditation of that fact and specify what action it has taken in relation to the recommendation.
- (6) The Authority undertakes to comply with any directions of the Director, Medicare Provider Eligibility and Accreditation for the purposes of giving effect to the recommendation of the independent body.
- (7) The powers conferred by this section are in addition to, and do not restrict, those conferred by section 23DNJ of the Act.

## 9 Quality assurance

- (1) On request of an independent body, the Authority undertakes to provide the independent body with copies of all quality assurance program reports and related information relating to the Authority and any of its employees.
- (2) Where the Authority participates in a quality assurance program for the purpose of proficiency testing, the Authority undertakes to authorise the provider of such quality assurance program to release information and reports generated as part of the quality assurance program to an independent body.
- (3) I undertake to take reasonable steps to obtain any necessary consents to enable me to provide reports or information to the independent body in accordance with subsection (1).
- (4) Nothing in this section obliges the Authority to provide reports or information to the independent body, or to authorise any other person to do so, in contravention of any law, but the Authority undertakes to take reasonable steps to obtain any necessary consents to enable me to provide reports or information to the independent body on request in accordance with subsection (1).

## 10 Notice of Matters Affecting Approval of Premises

The Authority undertakes to notify the Director, Medicare Provider Eligibility and Accreditation if any of the following occur:

- (a) the Authority or an independent body believe that the approved premises or any part of the approved premises ceases to comply with the accreditation materials defined in the *Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017*, or principles made in substitution of those principles;

- (b) where the approved premises comprise or include a laboratory that was a State accredited laboratory when the Minister approved it as an accredited pathology laboratory under subsection 23DN(1) of the Act, the laboratory ceases to be a State accredited laboratory;
- (c) there is a change to the proprietor of the approved premises;
- (d) any part of the approved premises ceases to be operative;
- (e) the Authority acquires, or commences to operate from, any premises additional to or in substitution for the approved premises;
- (f) there is a change in the name of the Authority;
- (g) there is a change in the Approved Pathology Practitioners, or senior scientist responsible for any services rendered in the premises, employed by the Authority;
- (h) there is a change in the Authority's address;
- (i) there is a change in the address of the approved premises or any part of the premises;
- (j) there has been a change in the directors, officers or principal shareholders of the Authority.

## **11 Notice to practitioners, patients or other persons**

- (1) The Authority undertakes to notify in writing any practitioner, participating nurse practitioner, participating midwife, patient or other person requesting or relying on the services rendered by the Authority if the approval of the Authority to render those services has been revoked, varied or refused by the Minister.
- (2) A notice under subsection (1) shall be restricted to services rendered to practitioners, participating nurse practitioners, participating midwives, patients or other persons who, according to a report of the independent body, may have received inaccurate or otherwise unreliable reports.
- (3) The Authority undertakes to provide a notice under subsection (1) within 5 working days of being notified that the approval of the Authority to render services has been revoked, varied or refused.
- (4) In the event that the Authority is unable to comply with subsection (1), the Authority undertakes to provide such assistance as requested by the Director, Medicare Provider Eligibility and Accreditation, which will enable such a notice to be given on behalf of the Authority.

## **12 Request and use of information**

- (1) If:
  - (a) the Director, Medicare Provider Eligibility and Accreditation; or
  - (b) an Assistant Secretary in the Provider Benefits Integrity Division of the Department of Health;

makes a written request to the Authority to provide any relevant information specified in the request relating to the premises or the services rendered by the Authority, including any matter arising out of this undertaking, the Authority undertakes to provide that information to the Director, Medicare Provider Eligibility and Accreditation or the Assistant Secretary in the Provider Benefits Integrity Division of the Department of Health.

- (2) The Authority acknowledges that information provided pursuant to this undertaking may be copied, disseminated or otherwise made available to any of the following:
  - (a) the independent body;
  - (b) officers of the Department of Health;
  - (c) persons performing the duties of an officer of the Department of Health;
  - (d) the Chief Executive Medicare;
  - (e) Departmental employees as defined in the *Human Services (Medicare) Act 1973*.
- (3) Information that may be requested under subsection (1) includes, without limitation:
  - (a) copies of agreements, arrangements or contracts under which the Authority employs or engages staff at its premises; and
  - (b) information relating to goods or services or both goods and services rendered by the Authority to a treating practitioner who requests or intends to request services from the Authority or an APP employed or engaged by the Authority, including goods to facilitate the collection of pathology specimens.
- (4) This section does not require the Authority to provide information that contains clinical details relating to a patient.

### **13 Agreements, arrangements or contract of employment with Approved Pathology Practitioner**

- (1) The Authority undertakes to ensure that no service is rendered in a laboratory owned by the Authority unless that service is rendered by or on behalf of an APP in accordance with an agreement, arrangement or contract of employment between the Authority and APP.
- (2) The Authority undertakes to ensure that any contract of employment or other agreement or arrangement between the Authority and an APP and any amendment or variation thereto is in writing signed by all the parties and does not, in any way, control the APP in the discharge of his or her responsibilities as set out in the APP's undertaking.

### **14 No inducement to use services**

- (1) The Authority undertakes to ensure that no request for the services of the Authority will be accepted from, or services rendered to, a practitioner, participating nurse practitioner, participating midwife or other person where any benefit or incentive (other than an item set out in Part 3 of this Schedule) has been directly or indirectly offered or supplied to the practitioner, participating nurse practitioner, participating midwife or person or his or her employer by the Authority or a person acting for or on behalf of, or associated with, the Authority.
- (2) The Authority undertakes not to enter into an arrangement that induces a medical practitioner employed by the Authority to request services from the Authority rather than another APA by:
  - (a) directly or indirectly offering an advantage to the medical practitioner; or
  - (b) directly or indirectly coercing the medical practitioner.

### **15 Accounts for services rendered by employed APP**

The Authority undertakes to ensure that where a service has been rendered by or on behalf of an APP employed by the Authority, an account for fees in relation to that service will be raised by the Authority on behalf of that APP. Such account will include,

and be supported by, information and particulars required under the Act.

## **16 Each entity to hold one approval as a pathology authority**

- (1) The Authority undertakes to consolidate, wherever possible, the business structure of the Authority such that only one approval is granted to any entity.
- (2) If:
  - (a) the Authority is part of a corporate structure comprising parent and subsidiary companies; and
  - (b) the subsidiaries are 100% owned by the parent company;

the Authority undertakes to, as far as is possible, consolidate the corporate structure such that only one approval as a pathology authority is available to that corporate structure.

## **17 Provision of information to prospective vendor or lessor of premises on or from which ACC to be operated**

- (1) The Authority undertakes to provide a copy of Part IIBA of the Act to any person from whom it proposes to purchase, lease or sub-lease premises on or from which the Authority has approval to operate or proposes to seek approval to operate an APL or ACC.
- (2) The undertaking in this section applies whether or not the Authority has previously owned, leased or sub-leased the premises.

## **18 Time and method of complying with undertakings**

- (1) The Authority must comply with any obligation imposed by this undertaking within 14 days of the obligation arising, unless otherwise specified.
- (2) Any information the Authority is required by this undertaking to provide to the Director, Medicare Provider Eligibility and Accreditation must be:
  - (a) delivered or posted to

The Director, Medicare Provider Eligibility and Accreditation  
Department of Human Services  
PO Box 1001  
Tuggeranong DC ACT 2901

Or another address specified by the Department by notice in writing to the Authority; or

- (b) emailed to [co\\_gp.manager.pathology@humanservices.gov.au](mailto:co_gp.manager.pathology@humanservices.gov.au).
- (3) Any information provided under paragraph 18(2)(a) must be signed by the Authority or by a person authorised in writing to sign on behalf of the Authority.
- (4) The Authority undertakes to take adequate steps to ensure that only authorised persons have access to its email system.
- (5) The Authority acknowledges that section 163 of the *Evidence Act 1995* will apply to any document posted to the Authority by the Department of Human Services at the address nominated in the application in support of which this undertaking is given or at such

other address as may later be provided by the Authority in writing to the Department of Human Services.

## **Part 2—Legislation**

*Health Insurance Act 1973*

*Health Insurance Regulations 1975*

*Human Services (Medicare) Act 1973*

*Human Services (Medicare) Regulations 2017*

*Health Insurance (Pathology) (Fees) Act 1991*

*Health Insurance (Approved Pathology Specimen Collection Centres) Tax Act 2000*

*Health Insurance (Pathology Services) Regulations 1989*

*Health Insurance (Pathology Services Table) Regulations 2017*

*Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017*

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

*Health Insurance (Pathologist-Determinable Services) Determination 2015*

*Health Insurance (Permitted Benefits-Pathology Services) Determination 2008*

*Health Insurance (Prescribed Pathology Services) Determination 2011*

*Health Insurance (Eligible Pathology Laboratories) Determination 2015*

## **Part 3—Items an Authority may provide requesting practitioners**

Note: In general, these are items which can only be used for the collection of specimens for pathology testing or, if other uses are possible, when supplied by APPs to referrers, will only be used for collection purposes. These are mostly single use items employed in the collection of pathology samples. These are the only items/services an APP/APA may supply free of charge, discounted or on a non-commercial basis, to a practitioner that requests or, intends to request, pathology services. There is no obligation for a pathologist to supply any of the accepted items to a requesting practitioner.

### **Blood collection**

- Needle Barrel Holders;
- Vacutainer (or equivalent) needles;
- Syringes 5mls or larger;
- Needles 21, 23 gauge;
- Alcowipes (or similar individual alcohol wipes);
- Spreaders for blood films;
- Small test tube racks;

### **Cervical cytology collection materials**

- Spray fixative;
- Cervix spatulas;
- Cyto brush;
- Direct to vial kits;
- Slides and slide carriers/holders;

### **Histology**

- Formalin or other fixative;
- Appropriate containers and media for specimens;
- Punch biopsy;



## **Microbiological specimens**

- All microbiological or virology swabs and transport media;
- Urine containers;
- Faeces containers;
- Paediatric urine collection kits;
- Chlamydia specific collection and transport receptacles;
- TB specific collection receptacles;
- Blood culture bottles;
- Petri dishes;
- Specimen biohazard bags/rubber bands;

## **Non cervical cytology**

Appropriate containers and media for urine, sputum and other body fluid cytology and cytology samples collected directly from tissues by the procedure of Fine Needle Aspiration Cytology (FNA);

## **Biochemistry**

- Timed urine (eg 24 hour) collection containers;
- Faecal fat collection containers;
- Glucose drink for GTT;
- Centrifuges, but to remain the property of APA, and only if practice demographics (in terms of time) from laboratory are such that failure to separate sera/plasma will damage specimen;

## **Stationery/Instruction Sheets**

- Paper or electronic request pads/forms/software;
- Medicare assignment forms DB3, including software facilitating electronic assignment;
- Repatriation assignment forms, including software facilitating electronic assignment;
- Telephone result pads;
- Stock request pads;
- Miscellaneous forms eg tube guides, practice information handbooks;
- All patient instruction sheets/education material;

## **Other**

- Fridge, where refrigeration is vital for the preservation of specimens (ie Laboratory being a long distance from collection point). Fridge must be labelled with Pathology Company name, and used exclusively for pathology purposes;
- Insulated containers such as eskies for specimen transport (must be labelled as property of laboratory);
- Other specimen transport containers (must be labelled as property of laboratory);
- Specimen pick up receptacles (eg night boxes), must be labelled as property of laboratory;
- Pathology download software specifically to retrieve pathology results for the laboratory. Pathology download software which is part of a larger suite should not be provided – where additional functionality cannot be separated from the software, a written licence agreement at normal commercial rates must exist between the APA and requesting practitioner or,

agreement must be established in writing prohibiting use of non-pathology software reporting components.

- Disposable vaginal speculums

## Part 4—Execution of undertaking

I/We\* \_\_\_\_\_

(\* name of applicant – as detailed on page 1)

apply to become an approved pathology authority and hereby give the undertaking recorded in this Schedule to the Minister. I/we acknowledge that a breach of this undertaking may be referred to a Medicare Participation Review Committee (MPRC) in accordance with the Act and, pursuant to section 124FB of the Act, the MPRC may make a number of determinations including that Medicare payments should not be payable for up to 5 years.

I/we request the Minister or a delegate of the Minister to accept the undertaking under section 23DF of the Act. I/we certify that all information in this application is true and correct.

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Position: \_\_\_\_\_

Position: \_\_\_\_\_

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_

Address: \_\_\_\_\_

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Witness (see 'Applicant Instructions' for detail on witness requirements & execution of undertaking)

I, \_\_\_\_\_, hereby assert that the applicant is known to me or, if not known, I am satisfied as to her/his identity and did witness the signing of this instrument before me on this day.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

Address: \_\_\_\_\_

**Partnership**

Name, ABN (if applicable) and signature of each partner and date signed.

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(name in block letters) (ABN if applicable) (signature) (date)

All partners to sign. If insufficient space, this page can be copied and signed. If a partner is a corporation, show company name and position held by natural person authorised and signing on behalf of the company.