Australian Government

Medicare Australia

Approved Pathology Authority Application

Application for acceptance by the Minister for Health and Ageing of an Approved Pathology Authority undertaking under section 23DF of the *Health Insurance Act 1973*

Contents

Instructions and guide to your application **Page number**

Your undertaking at a glance

Instructions and guide to your application

Introduction and administrative matters

A pathology service will not attract Medicare benefits unless performed by or on behalf of an approved pathology practitioner within an approved laboratory. The laboratory proprietor must be an Approved Pathology Authority.

For this purpose, proprietor means an Approved Pathology Authority, which has effective control of:

a) the laboratory premises and holder of an estate or interest in the premises,
b) the use of equipment used in the laboratory, and
c) the employment of staff in the laboratory.

Checklist for completion and return of application and undertaking

- Applicants will need to complete all questions relevant to their application within pages 6 to 10. All applicants must complete question three on page 9

- The Undertaking must be signed and witnessed at page 23.

For a company

Insert the company name after 'I/we' on page 23 and sign the document, as applicable for your company, either:

- **without a seal,** signed by
  a) 2 directors of the company;
  b) a director and company secretary of the company; or
  c) for a proprietary company that has a sole director who is also the company secretary – that director[1]

- **with a seal** – if the fixing of the seal to the document is **witnessed by**
  a) two directors of the company;
  b) a director and company secretary or the company; or
  c) for a proprietary company that has a sole director which is also the company secretary – that director[2]

For a partnership

Insert partnership name after 'I/we' on 23, such as – 'The partners of the partnership known as ……..'

Page 24 must be used such that all partners sign.

Companies who are partners should sign as set out above for company applicants.

[1]In accordance with section 127(1) of the *Corporations Act 2001*
[2]In accordance with section 127(2) of the *Corporations Act 2001*

For a natural person

Must be signed by the applicant and witnessed at time of signing

Witnessing – other than company applicants

In the case of partnership or natural person applicant, a witness may include such person as a member of the Institute of Chartered Accountants, certified practising accountant, barrister, solicitor, a legal practitioner, justice of the peace, post office manager and other persons ordinarily qualified to witness a statutory declaration.

- **Payment of fee**

  Approval is usually for a period of 12 months and subject to payment of a fee. The fee is $1500 and can be made by cheque, payable to Medicare Australia. A receipt will not be issued unless requested.

- **Late applications – where applying for renewal of approval**

  Applicants are encouraged to lodge renewal applications and undertakings before current approvals expire. Failure to do so will result in loss of Medicare benefits.

- **Submitting your application and undertaking**

  When complete, your application and undertaking may be submitted to the address detailed below. A pre-addressed envelope is provided with renewal applications.

Questions and clarification

Questions and clarification in relation to this document should be directed to:

Pathology Registration
Medicare Australia
GPO Box 9822
MELBOURNE VIC 3001

Ph: (03) 9605 7013 Fax: (03) 9605 7984
Email: vic.provider.liaison@medicareaustralia.gov.au

For information about pathology services and Medicare benefits

Information about pathology services and Medicare benefits is available within the current Medicare Benefits Schedule book printed and published by the Department of Health and Ageing. A copy is available from the Department of Health and Ageing or at www.health.gov.au.

Instructions for completing pages 6 - 10

Page 6 – Applicant details

An applicant may be a natural person, a partnership, a body corporate, a state government, territory or public authority. The appropriate type should be selected and requested details entered on page 6.

A renewal application should include the number previously provided to the Approved Pathology Authority.

Page 7 – Trading name and contact details

A trading name to be used by the applicant must be registered in the state or territory of applicants place of business. A trading name must be registered in the name of the applicant. Registration expiry date is required and assists when Medicare Australia confirms details with the Registrar of Business Names.

The applicant may provide an alternative contact person for the purpose of administrative matters. By entering a contact person the applicant indicates the contact to have authority to handle administrative matters on behalf of the applicant.

Page 8 – Company details

A body corporate applicant is required to detail all directors and principle office bearers. In the event of a change in these details, the applicant must advise Medicare Australia within 14 days. Also required are the top 10 shareholders as at date of application.

Page 9 – Partnership details

A partnership must detail all partners – both natural persons and body corporate partners – and indicate share of partnership held by each.

Page 9– Questions about applicant and persons

Question three on page nine asks a series of questions. When considering an application for approval, it is necessary to consider if any person or persons in an employee, business or financial relationship with the applicant are a 'relevant person' as defined at section 23DA of the *Health Insurance Act 1973*.

A person may become a 'relevant person' for many reasons, including breach and alleged breach of undertaking or, on conviction of a 'relevant offence' – which is also defined at section 23DA.

The questions seek to identify notices or convictions served on the applicant or other persons in an employee, business or financial relationship with the applicant. The existence of which will render them a 'relevant person' and further detail will be required.

Page 10 – Additional information

Space for additional information, should it be required.

Australian Government

Medicare Australia

Application for acceptance as an Approved Pathology Authority

Section 23DF *Health Insurance Act 1973*

Applicant details and indication of applicant type (for example body corporate, partnership)

APA number – for renewal applications

Please tick a box and fill in corresponding section

☐ **Body corporate**

Company name

Registered address

Number

Street name

Suburb State Postcode

ABN

☐ **State government, territory government or a public authority**

Company name

Registered address

Name

Address

Suburb State Postcode

ABN

☐ **Partnership**

Company name

Registered address

Name

Address

Suburb State Postcode

ABN

☐ **Natural person**

Company name

Registered address

Name

Address

Suburb State Postcode

ABN

Trading name (if any – must be owned by the applicant)

Registered name

Registration expires

Contact details for applicant

Contact person

☐ Details as above

Address for correspondence

☐ Details as above

Number/ Po Box

Street name

Suburb State Postcode

Contact telephone number

Fax number

Email address

(by entering email address, you acknowledge that all notices may be given to you by email)

Please proceed to the question indicated for your applicant type:

Body corporate……Go to question 1

Partnership…… ……Go to question 2

State government, territory government or public authority……Go to question 3

Natural person……Go to question 3

1. Body corporate

NOTE: The form for this question can be copied and the extra page/s attached to the application where the space is insufficient (for example a partnership of a number of companies)

(a) List directors – if a sole director company, please indicate

1	6
2	7
3	8
4	9
5	10

(b) Names and positions held by principal office bearers of the applicant (for example, manager, executive director).

Name	Tile of office held
1	
2	
3	
4	
5	

(c) Names of principal shareholders (top 10) in order of shareholding.

Principle shareholders at date of application	Aprox % of shareholding at date of application
1	%
2	%
3	%
4	%
5	%
6	%
7	%
8	%
9	%
10	%

Go to question 3

2. Partnership

Please detail each partner.

Natural person/body corporate partners	Percentage share of partnership	ABN (if applicable)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		

3. Is the applicant or, to the applicant's knowledge (having made reasonable inquiry*), any person with whom the applicant has or proposes to have a financial, employee/employer or business relationship, a person:

a) to whom notice has been given under subsection 23DL(1) or 23DM(1) of the Act or in relation to whom notice has been given to a chairperson of a Medicare Participation Review Committee under subsections 23DL(4), 23DM(4)or 124D(2) of the Act? Yes ☐ No ☐

b) to whom notice has been given under subsection 124FA(3) or 124FE(3) of the Act? Yes ☐ No ☐

c) in relation to whom a Medicare Participation Review Committee has made a determination under section 124F, 124FB, 124FC or 124FF of the Act? Yes ☐ No ☐

d) to whom notice has been given under subsection 102(1) of the Act/ Yes ☐ No ☐

e) to whom a final determination under section 106T of the Act has been made? Yes ☐ No ☐

f) who has been convicted of a relevant offence as defined in s23DA of the Act? Yes ☐ No ☐

If you have answered 'yes' to question 3 (a,b,c,d,e,or f), please provide details.
Details should consist of name, company name and provider number if applicable

***Note**: 'Reasonable inquiry'; you will be required to provide some information about another person when making your application. Reasonable inquiry means that, unless you are certain of the situation, you will be expected to ask the person involved to ensure that your answer is as accurate as can reasonably be expected. You will not be expected to make exhaustive investigations. If you are unsure about a certain response you should seek clarification from Medicare Australia.

4. Additional information

Please attach any additional information if required.

APA undertaking

Part 1 – Compliance with legislation

1.1 As an authorised representative of the authority, I have read and familiarised myself with the provisions of the legislation listed in Schedule 1: Legislation (the legislation) as summarised in the Medicare Benefits Schedule book current at the date of my giving this undertaking.

1.2 The authority undertakes to comply with the legislation, as in force from time to time and set out in Schedule 1: Legislation, or any legislation made in substitution for that legislation.

1.3 The authority undertakes not to take any action that would constitute a relevant offence as defined at subsection 124B(1) of the Act.

1.4 The authority acknowledges that a failure to comply with the requirements of parts 1.2 or 1.3 constitutes a breach of this undertaking whether or not that failure has been, or is likely to be, proven in court proceedings.

1.5 The authority undertakes to comply with the outline of arrangements and assessment criteria set out in the Medicare Benefits Schedule book, as in force and amended from time to time.

1.6 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.

Part 2 – Persons acting on behalf of the authority

2.1 Where whether by way of contract of employment or otherwise, and in relation to a matter in relation to which this undertaking is given, any person:

(i) acts on behalf of the authority; or

(ii) is in a position to influence or control the activities of the authority; or

(iii) to the knowledge of the authority, holds themselves out to act on behalf of the authority

the authority undertakes to ensure that such a person is aware of this undertaking and the authority acknowledges that it shall be responsible and accountable for any act in breach of this undertaking by such person or persons described in this part.

2.2 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.

Part 3 – Financial affairs

3.1 The authority undertakes to inform the Manager Diagnostic Accreditation if any of the following circumstances occur:

(i) 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;

(ii) a qualified audit report has been made relating to the financial affairs of the authority or its management of the approved premises.

3.2 Where the authority provides the Manager Diagnostic Accreditation with information referred to in Part 3.1 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.

3.3 The authority undertakes to inform the Manager Diagnostic 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.

Part 4 – Dealings with relevant person

4.1 Where the authority can reasonably be expected to know, the authority undertakes to inform the Manager Diagnostic Accreditation if any of the following circumstances occur:

(i) the authority becomes a relevant person;

(ii) the authority obtains control of the operations of a relevant person;

(iii) any person who derives, or can reasonably be expected to derive either directly or indirectly) financial benefit from the conduct by the authority of business at the approved premises becomes a relevant person;

(iv) the authority comes to have a financial association with a relevant person;

(v) a director, secretary or officer of the authority becomes a relevant person;

4.2 The authority undertakes not to employ any relevant person or enter into a contract or understanding with such a person.

Part 5 – Information to be accurate

5.1 The authority undertakes to ensure that information, which it may provide to Medicare Australia, including that relating to claims for payment is, accurate and complete.

5.2 The authority undertakes to advise the Manager Diagnostic 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 and ACC.

5.3 The authority undertakes to inform Medicare Australia in writing within 14 days should it become aware, or have reason to believe, that inaccurate or incomplete information has been provided to Medicare Australia.

5.4 The authority undertakes to provide Medicare Australia 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 Medicare Australia in writing within 14 days of such request.

Part 6 – Inspection of premises

6.1 The authority undertakes, at any reasonable time and with 12 hours notice, to permit a person or persons authorised by the Manager Diagnostic Accreditation, and, on production of such authorisation, to:

(i) enter and inspect the premises;

(ii) inspect any equipment used in relation to the rendering of services in the premises;

(iii) inspect any process in the rendering of services in the premises;

(iv) inspect documents and other records related to staffing, supervision, quality assurance programs and the rendering of services in the premises;

(v) make and retain copies of, take and retain extracts from, any such documents or records detailed at part 6.1(iv) with proper regard for individual patient confidentiality.

6.2 A time shall be deemed to be reasonable if it is between the hours of 9am and 5pm on a weekday or at another time when the premises are operating.

6.3 An inspection as described in part 6.1 may be undertaken without notice and at other times if the Minister for Health and Ageing or Chief Executive Officer of Medicare Australia certifies in writing that the inspection is necessary in the interests of public safety.

6.4 The powers conferred by this clause are in addition to, and do not restrict, those conferred by section 23DNJ of the Act.

Part 7 – Cooperation with independent body

7.1 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, and on production of such authorisation, to:

(I) enter and inspect the premises;

(ii) inspect any equipment used in relation to the rendering of services in the premises;

(iii) inspect any process in the rendering of services in the premises;

(iv) inspect documents and other records related to staffing, supervision, quality assurance programs and the rendering of services in the premises;

(v) make and retain copies of, or take and retain extracts from, any such documents or records detailed at part 7.1(iv) with proper regard for individual patient confidentiality.

7.2 The authority undertakes to provide to an independent body such information, including reports and information relating to quality assurance activities, as it reasonably requests.

7.3 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.

7.4 If it becomes apparent to the authority that it is not able to comply with a recommendation of the independent body referred to in part 7.3 or is not able to comply within the period recommended by the independent body, the authority undertakes to advise the Manager Diagnostic Accreditation of that fact and specify what action it has taken in relation to the recommendation.

7.5 The authority undertakes to comply with any directions of the Manager Diagnostic Accreditation for the purposes of giving effect to the recommendation of the independent body.

7.6 The powers conferred by this clause are in addition to, and do not restrict, those conferred by section 23DNJ of the Act.

Part 8 – Quality assurance

8.1 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.

8.2 Where the authority participates in a quality assurance program for the purposes 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.

Part 9 – Notice of matters affecting approval of premises

9.1 The authority undertakes to notify the Manager Diagnostic Accreditation if any of the following circumstances occur:

(i) the approved premises or any part of the approved premises ceases to comply with the accreditation materials set out in Schedule 1 of the *Health Insurance (Accredited Pathology Laboratories-Approval) Principles 2002,* as in force from time to time, identified by either the authority or independent body;

(ii) 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;

(iii) there is a change to the proprietor of the approved premises;

(iv) any part of the approved premises ceases to be operative;

(v) the authority acquires, or commences to operate from, any premises additional to or in substitution for the approved premises;

(vi) there is a change in the name of the authority;

(vii) there is a change in the approved pathology practitioners, or senior scientist responsible for any services performed in the premises, employed by the authority;

(viii) there is a change in the authority's address;

(ix) there is a change in the address of the approved premises or any part of the premises;

(x) There has been a change in the directors, officers or principal shareholders of the authority.

Part 10 – Notice to practitioners, patients or other persons

10.1 The authority undertakes to notify in writing any practitioner, patient or other person requesting or relying on the services provided by the authority if the approval to undertake those services has been revoked, varied or refused by the Minister.

10.2 A notice under part 10.1 shall be restricted to services provided to practitioners, patients or other persons who, according to a report of the independent body, may have received inaccurate or otherwise unreliable reports.

10.3 The authority undertakes to provide a notice pursuant to part 10.1 within five working days of being notified that services have been revoked, varied or refused.

10.4 In the event that the authority is unable to comply with part 10.1 the authority undertakes to provide such assistance as requested by Manager Diagnostic Accreditation, which will enable such a notice to be given on behalf of the authority.

Part 11 – Request and use of information

11.1 If the Manager Diagnostic Accreditation makes a written request to the authority to provide any relevant information specified in the request relating to the premises or the services provided by the authority, including any matter arising out of this undertaking, the authority undertakes to provide that information to the Manager Diagnostic Accreditation.

11.2 The authority acknowledges that information provided pursuant to this undertaking may be copied, disseminated or otherwise made available to officers and the independent body.

Part 12 – Agreements, arrangements or contract of employment with Approved Pathology Practitioners

12.1 The authority undertakes to ensure that no service is performed in a laboratory owned by the authority unless that service is performed by or on behalf of an Approved Pathology Practitioner in accordance with an agreement, arrangement or contract of employment between the authority and APP.

12.2 The authority undertakes to ensure that any contract of employment or other agreement 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 undertaking of the said APP.

Part 13 – No inducement to use services

13.1 The authority undertakes to ensure that no request for the services of the authority will be accepted from, or services provided to, a practitioner or other person where any benefit or incentive (other than an item set out in Schedule 2) has been directly or indirectly offered or supplied to the practitioner or person or the employer of that practitioner or person by the authority or a person acting for or on behalf of, or associated with, the authority.

13.2 The authority undertakes not to enter into an arrangement that directly or indirectly offers an advantage to, or directly or indirectly coerces, a medical practitioner employed by the authority to request services from the authority rather than another APA.

Part 14 – Accounts for services rendered by employed APP

14.1 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 by the Act and the Medicare Benefits Schedule book.

Part 15 – Each entity to hold one approval as a pathology authority

15.1 The authority undertakes to consolidate, wherever possible, the business structure of the authority such that one approval is granted to any entity.

15.2 Where the authority is part of a corporate structure comprising parent and subsidiary companies and, such subsidiaries are 100 per cent owned by a 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.

Part 16 – Time and method of complying with undertakings

16.1 Where an obligation is placed upon an authority by this authority, the authority undertakes to comply with that obligation within 14 days of the event occurring that gives rise to the obligation, or such other time as specified in the relevant part.

16.2 Where an obligation is placed upon the authority by this undertaking that requires the Authority to give information to the Manager Diagnostic Accreditation, the information must be:

(i) in writing or by email;

(ii) if in writing signed by the authority or by a person authorised in writing to sign on behalf of the authority;

(iii) delivered or posted to

Pathology Registration
Medicare Australia
GPO Box 9822
MELBOURNE VIC 3001

or such other address as Medicare Australia has specified by notice in writing to the authority;

(iv) If the authority uses email to give such a notice the authority undertakes to take adequate steps to ensure that only authorised persons have access to the email function on computers of the authority and such notices shall be addressed to: vic.provider.liaison@medicareaustralia.gov.au

16.3 If the authority acknowledges that section 163 of the *Evidence Act 1995 (Cth)* will apply to any document posted to the authority by Medicare Australia at the address nominated in the application in support of which this undertaking is given or as may later be provided by the authority in writing to Medicare Australia.

Part 17 – Definitions

17.1 In this undertaking:

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

'Act' means the *Health Insurance Act 1973* as amended from time to time;

‘ACC’ means an approved collection centre, pursuant to section 23DNBA of the Act;

‘APA’ means an approved pathology authority, pursuant to section 23DF of the Act;

‘APP’ means an approved pathology practitioner, pursuant to section 23DC of the Act;

‘APL’ means an accredited pathology laboratory, pursuant to section 23DN of the Act;

‘Account’ means an itemised list of pathology services performed that may be eligible for payment under Medicare including a claim for assigned benefits pursuant to the Act;

‘Authority’ means the applicant providing details and undertaking for the purpose of approval as an Approved Pathology Authority (APA) pursuant to section 23DF of the Act;

‘Certified’ means a copy of a document where the copy has been authenticated by a referee as a true and accurate reproduction of the original. A referee may include persons such as – a member of the Institute of Chartered Accountants, certified practising accountant, barrister, solicitor, a legal practitioner, a medical practitioner, justice of the peace and other persons ordinarily qualified to witness a statutory declaration;

‘Entity’ means a legal entity;

‘Medicare Australia’ means a member of staff of Medicare Australia engaged pursuant to subsection 28(1) of the Medicare Australia Act 1973

‘Independent body’ has the same meaning as in the *Health Insurance (Accredited laboratories-Approval) Principles 2002* as amended from time to time or as included in any legislation made in substitution for those principles;

‘Laboratory’ means accredited pathology laboratory, given approval pursuant to section 23DN of the Act;

‘Manager Diagnostic Accreditation’ means the person for the time being holding, acting in, or performing the duties of the position titled Manager Diagnostic Accreditation within Medicare Australia;

‘Chief Executive Officer of Medicare Australia’ means the person for the time being holding the position titled Chief Executive Officer of Medicare Australia within Medicare Australia and includes an officer holding a valid delegation to make a particular decision in place of the Chief Executive Officer of Medicare Australia;
‘Medicare Benefits Schedule book’ means the book published by the Commonwealth Department of Health and Ageing generally in November of each year and forwarded to all medical practitioners;

‘Minister’ means, except where the reference is to an officer of the authority,

(i) an officer of the Commonwealth Department of Health and Ageing, or
(ii) a member of Medicare Australia, or

(iii) a member of the staff of Medicare Australia who is engaged pursuant to subsection 28(1) of the Act;

'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;

'Relevant person' means a person defined in paragraphs (a) to (f) of section 23DA of the Act, which, in summary, includes a person who: has been given a notice; received a determination; been convicted of a relevant offence; or, whom the Minister, on reasonable grounds, believes may have committed a relevant offence;

'Relevant offence' means an offence defined at section 23DA of the Act;

'Referring practitioner' means a medical practitioner who refers a request from a treating practitioner onto another APP or APA for testing.

'Scientist' means a person defined within subsection 23DNA(4) of the Act;

'Service' means pathology service(s) to which an item in the Medicare Benefits Schedule book relates and in respect of which Medicare benefit is payable;

'State accredited laboratory' means

(i) a pathology laboratory which is accredited pursuant to state legislation; and
(ii) in relation to a laboratory which is situated in Victoria, an accredited pathology laboratory under the *Pathology Services Accreditation Act 1984* of Victoria;

'Treating practitioner' means a medical practitioner responsible for the care, diagnosis and treatment of a patient;

A reference in this undertaking to writing, documents and records includes material in electronic form where recorded and submitted in accordance with information technology standards of Medicare Australia established pursuant to the *Electronic Transaction Act 1999*

Schedule 1: Legislation

Health Insurance Act 1973

Health Insurance Regulations 1975

Medicare Australia Act 1973

Medicare Australia Regulations 1973

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 2001

Health Insurance (Accredited Pathology Laboratories –Approval) Principles 2002

Health Insurance (Eligible Collection Centre) Approval Principles 2005

Health Insurance (Pathology-determinable Services) Determination 2000

Schedule 2: Items an authority may provide requesting practitioners

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 pathologists to referrers, will only be used for collection purposes. These are mostly single use items employed in the collection of pathology samples.

- **Blood collection**
  Needle barrel holders;
  Vacutainer (or equivalent tubes for collection);
  Syringes 5mls or larger;
  Needles 21, 23 gauge;
  Alcowipes (or similar individual alcohol wipes);
  Spreaders for blood files;
  Small test tube rack;

- **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 should be labelled with pathology company name, and used exclusively for pathology purposes;
  Insulated containers such as eskies for specimen transport, wet ice/dry ice (must be labelled as property of laboratory);
  Other specimen transport containers (must be labelled as property of laboratory);
  Specimen pick up receptacles (for example, night boxes), must be labelled as property of laboratory;
  Pathology down load 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 referring practitioner or, agreement must be established in writing prohibiting use of non-pathology software reporting components.

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. This list may be updated from time to time in consultation with the Royal College of Pathologists Australasia.

There is no obligation for a pathologist to supply any of the accepted items to a requesting practitioner.

Commonwealth of Australia

Health Insurance Act 1973

APPROVED PATHOLOGY AUTHORITY UNDERTAKING

For the purposes of section 23DF of the *Health Insurance Act 1973*

I/we* _____

(*name of applicant – detailed on page 6)

apply to become an approved pathology authority and hereby give this undertaking recorded in pages 11 to 21 of this instrument 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 five 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.

Please ensure your signing of this instrument is witnessed

Name: _____

Position: _____

Signature: _____

Date: _____

Address

Number
Street Name
Suburb
State Postcode

Name: _____

Position: _____

Signature: _____

Date: _____

Address

Number
Street Name
Suburb
State Postcode

Witness (see 'Applicant Instructions' for detail on witness requirements and 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

Number
Street Name
Suburb
State Postcode

Partnership

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

(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(date)
(name in block letters)	(Signature)	(ABN if applicable)	(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.