Australian Government
Services Australia

medicare

Application for approval, amendment or renewal of an approved pathology authority (HW011)

When to use this form

This form must be used by pathology authorities to apply for, amend or renew an existing approved pathology authority (APA) under section 23DF of the *Health Insurance Act 1973.*

Important information

Payment is not required until your undertaking has been accepted.

If your undertaking is accepted, a request for payment will be sent by standard mail and email, if you provided an email address on this form.

Payment must be received **within 14 days** of the date your undertaking was accepted or acceptance of your undertaking will be revoked and you will need to re-apply.

For renewal applications, make sure the date you sign the undertaking and send it to us is no more than 3 months before your current approval expires.

If your APA undertaking has expired, you will need to provide a letter of request telling us why your application is late. Backdated approvals can only be granted by the Services Australia delegate if your undertaking is accepted within one month of the previous approval's expiry date.

For more information

Go to **servicesaustralia.gov.au/medicarepathology** or call 1300 721 546 Monday to Friday, 8:30 am to 5 pm, Australian Eastern Standard Time.

Call charges may apply.

For more information about pathology, go to **health.gov.au**

Returning this form

STOP

Check that you have answered all the required questions and provide the requested documentation when you return this form. If the application is incomplete or incorrect, it will be returned and you will need to re-apply.

This form must be manually signed and witnessed.

Return all pages of the completed form and supporting documents:

- **online**, using your Provider Digital Access (PRODA) account and the Form upload function in Health Professional Online Services (HPOS). For more information, go to **servicesaustralia.gov.au/hpos**
- by post to
  Services Australia
  Pathology Registration
  GPO Box 9822
  MELBOURNE VIC 3001
- by fax to
  02 9895 3439 NSW/ACT
  08 8274 9307 SA/NT
  08 9214 8201 WA
  07 3004 5634 QLD
  03 9605 7984 VIC/TAS

Filling in this form

You can fill this form digitally in some browsers, or you can open it in Adobe Acrobat Reader. If you do not have Adobe Acrobat Reader, you can print this form and complete it.

If you have a printed form:

- Use black or blue pen.
- Print in BLOCK LETTERS.
- Where you see a box like this ☐ ***Go to 1*** skip to the question number shown.

Application type

1 This application is: **Tick one only**

for a new APA ☐ ***Go to 3***

to renew an existing APA ☐ *Go to next question*

to amend an existing APA ☐ *Go to next question*

Applicant's details

2 APA number

3 Authority name

4 Registered address

Postcode

5 Postal address (if different to above)

Postcode

MCA0HW011 2402

Authorised representative's details

6 **Read** this before answering the following question.

Access to HPOS will be linked to this APA. Once linked, HPOS will be a method of written communication for the APA. If you are an existing contact replacing an existing authorised representative, that person's administrator access in HPOS will be removed. Only an existing contact can replace an authorised representative. For any other changes, a separate authorisation letter must be provided by a senior executive of the APA.

Give details of each authorised representative

Authorised representative 1

Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Authorised representative's full name

Position held

PRODA Registration Authority (RA) number

Daytime phone number (including area code)

Mobile phone number

Email

This is the email address we will use to notify you of the outcome of your application.

Authorised representative 2

Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Authorised representative's full name

Position held

PRODA RA number

Daytime phone number (including area code)

Mobile phone number

Email

Proprietorship details

7 Australian Business Number (ABN)

or

Australian Company Number (ACN) if applicable

8 Registered trading name if any (must be owned by the applicant)

Date trading name registration expires (DD MM YYYY)

9 What is the nature of your proprietorship?

Individual ☐ ***Go to 10***
Partnership ☐ ***Go to 11***
Company ☐ ***Go to 12***
Government agency or public body ☐ ***Go to 16***

Individual's details

10 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name

First given name

Go to 18

Partnership

11 Give details of each partner

Partner 1

Full name of individual or company

Percentage share of partnership %

Australian Business Number (ABN) if applicable

Australian Company Number (ACN) if applicable

Partner 2

Full name of individual or company

Percentage share of partnership %

Australian Business Number (ABN) if applicable

Australian Company Number (ACN) if applicable

Partner 3

Full name of individual or company

Percentage share of partnership %

Australian Business Number (ABN) if applicable

Australian Company Number (ACN) if applicable

Partner 4

Full name of individual or company

Percentage share of partnership %

Australian Business Number (ABN) if applicable

Australian Company Number (ACN) if applicable

If you need more space, provide a separate sheet with details.

▶ *Go to 18*

Company

12 Registered business name

13 Australian Company Number (ACN)

14 Provide the full name of all directors
If it is a sole director company, please indicate

1.
2.
3.
4.
5.

If you need more space, provide a separate sheet with details.

15 Provide the full name of all principal shareholders on the date of application in order of their shareholding

Shareholder 1

Full name

Approximate percentage of shareholding %

Shareholder 2

Full name

Approximate percentage of shareholding %

Shareholder 3

Full name

Approximate percentage of shareholding %

Shareholder 4

Full name

Approximate percentage of shareholding %

Shareholder 5

Full name

Approximate percentage of shareholding %

If you need more space, provide a separate sheet with details.

▶ *Go to 18*

Government agency or public body

16 Government agency or public body registered business name

17 Australian Company Number (ACN)

Principal office bearer's details

18 **Read** this before answering the following question.

Answering the following question is **mandatory** for **all proprietor types**. Failure to complete this section will deem your application as incomplete.

Provide the full name and position of all principal office bearers of the applicant (for example, manager, executive director)

Principal office bearer 1

Full name

Position held

Principal office bearer 2

Full name

Position held

Principal office bearer 3

Full name

Position held

Principal office bearer 4

Full name

Position held

Principal office bearer 5

Full name

Position held

Principal office bearer 6

Full name

Position held

If you need more space, provide a separate sheet with details.

19 **Read** this before answering the following question.

This question refers to the applicant or any person with whom the applicant has, or proposes to have, a financial, employee/employer or business relationship. You will need to make a reasonable inquiry about any other person.

Reasonable inquiry means that:

- you will be required to provide some information about another person when making your application, **and**
- 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 not sure about a certain response you should seek clarification from us.

Is the applicant or any person with whom you have, or propose to have, a financial, employee/employer or business relationship, a person:

(a) to whom notice has been given under subsection 23DL(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) or section 124D of the Act? No ☐ Yes ☐

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

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

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

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

(f) who has been convicted of a relevant offence as defined in section 23DA of the Act? No ☐ Yes ☐

20 If you have answered 'Yes' to any of questions (a) to (f) at question 19, give details of name, company name and provider number

If you need more space, provide a separate sheet with details.

Additional information

21 Provide any additional information to support this application

If you need more space, provide a separate sheet with details.

Schedule 2 – Approved Pathology Authority Undertaking

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

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 and Aged Care 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 and Aged Care.

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.

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

Director, Medicare Providers, Pathology and Diagnostic Imaging Section means the person from time to time holding, acting in, or performing the duties of the position titled Director, Medicare Providers, Pathology and Diagnostic Imaging Section within Services Australia.

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.

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 Providers, Pathology and Diagnostic Imaging Section 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 Providers, Pathology and Diagnostic Imaging Section 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 Providers, Pathology and Diagnostic Imaging Section 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 Providers, Pathology and Diagnostic Imaging Section 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 Services Australia, including that relating to claims for payment is, accurate and complete.

(2) The Authority undertakes to advise the Director, Medicare Providers, Pathology and Diagnostic Imaging Section 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 Services Australia in writing **within 14 days** should it become aware, or have reason to believe, that inaccurate or incomplete information has been provided to the Agency.

(4) The Authority undertakes to provide Services 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 the Agency 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 Providers, Pathology and Diagnostic Imaging Section 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 Providers, Pathology and Diagnostic Imaging Section 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 Providers, Pathology and Diagnostic Imaging Section 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

(1) The Authority undertakes to notify the Director, Medicare Providers, Pathology and Diagnostic Imaging Section 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 Providers, Pathology and Diagnostic Imaging Section, 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 Providers, Pathology and Diagnostic Imaging Section, or

(b) an Assistant Secretary in the Provider Benefits Integrity Division of the Department of Health and Aged Care

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 Providers, Pathology and Diagnostic Imaging Section or the Assistant Secretary in the Provider Benefits Integrity Division of the Department of Health and Aged Care.

(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 and Aged Care

(c) persons performing the duties of an officer of the Department of Health and Aged Care

(d) the Chief Executive Medicare

(e) Agency 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 APP

(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 Providers, Pathology and Diagnostic Imaging Section must be:

(a) delivered or posted to

The Director, Medicare Providers
Pathology and Diagnostic Imaging Section
Services Australia
PO Box 1001
Tuggeranong DC ACT 2901

or another address specified by the Agency by notice in writing to the Authority, or

(b) emailed to
co.gp.manager.pathology@servicesaustralia.gov.au

There may be risks with sending personal information through unsecured networks or email channels.

(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 Services Australia 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 Services Australia.

Part 2 – Legislation

Health Insurance Act 1973

Health Insurance Regulations 2018

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 2020

Health Insurance (Pathology Services Table) Regulations 2020

Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2017

Health Insurance (Approvals for Eligible Collection Centres) Principles 2020

Health Insurance (Pathologist-determinable Services) Determination 2015

Health Insurance (Permitted Benefits-Pathology Services) Determination 2018

Health Insurance (Prescribed Pathology Services) Determination 2011

Health Insurance (Eligible Pathology Laboratories) Determination 2015

Part 3 – 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 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 (for example, 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 (for example, tube guides, practice information handbooks)
- All patient instruction sheets/education material

Other

- Fridge, where refrigeration is vital for the preservation of specimens (that is, 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 (for example, 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

Privacy notice

22 The privacy and security of your personal information is important to us, and is protected by law. We collect this information so we can process and manage your applications and payments, and provide services to you. We only share your information with other parties where you have agreed, or where the law allows or requires it. For more information, go to **servicesaustralia.gov.au/privacypolicy**

Undertaking by a company, government agency, public body or individual

Ensure your signing of this instrument is witnessed. Execution of documents by a company must be in accordance with section 127 of the *Corporations Act 2001*.

23 I/we *(full name of pathology authority as detailed on page 1 in block letters)*

apply to become an approved pathology authority and hereby give this undertaking recorded in this Schedule to the Minister.

I/We declare that:

- the information I/we have provided in this form is complete and correct.

I/We acknowledge that:

- a breach of this undertaking may be referred to a Medicare Participation Review Committee in accordance with the Act and, pursuant to section 124FC of the Act, the Medicare Participation Review Committee may make a number of determinations including that Medicare payments should not be payable for up to 5 years.

I/We request that:

- the Minister or a delegate of the Minister accept the undertaking under section 23DF of the Act.

I/We understand that:

- giving false or misleading information is a serious offence.

Signatory 1

Full name

Position held

Full address

Postcode

Signature

On completion, print and sign in front of a witness

Date (DD MM YYYY)

Signatory 2

Full name

Position held

Full address

Postcode

Signature

On completion, print and sign in front of a witness

Date (DD MM YYYY)

Witness's acknowledgement

The witness must be on the list of authorised witnesses and have a connection to Australia or be a notary public. For more information, go to **ag.gov.au**

24 I *(full name of witness in block letters)*

of *(full address)*

Postcode

hereby assert that the applicant(s) are known to me or, if not known, I am satisfied as to their identity and did witness the signing of this instrument before me on this day.

Witness's signature

Date (DD MM YYYY)

Undertaking by a partnership

Ensure your signing of this instrument is witnessed. All partners must sign this instrument. If there is insufficient space, this page can be copied and signed. If a partner is a corporation, provide the company name and position held by a natural person authorised and signing on behalf of the company. Execution of documents by a company must be in accordance with section 127 of the *Corporations Act 2001*.

25 I/We *(full name of pathology authority as detailed on page 1 in block letters)*

apply to become an approved pathology authority and hereby give this undertaking recorded in this Schedule to the Minister.

I/We declare that:

- the information I/we have provided in this form is complete and correct.

I/We acknowledge that:

- a breach of this undertaking may be referred to a Medicare Participation Review Committee in accordance with the Act and, pursuant to section 124FC of the Act, the Medicare Participation Review Committee may make a number of determinations including that Medicare payments should not be payable for up to 5 years.

I/We request that:

- the Minister or a delegate of the Minister accept the undertaking under section 23DF of the Act.

I/We understand that:

- giving false or misleading information is a serious offence.

Partnership signatory 1

Full name (block letters)

Company name (if applicable)

Australian Business Number (ABN) if applicable

Australian Company Number (ACN) if applicable

Full address

Postcode

Signature

On completion, print and sign in front of a witness

Date (DD MM YYYY)

Partnership signatory 2

Full name (block letters)

Company name (if applicable)

Australian Business Number (ABN) if applicable

Australian Company Number (ACN) if applicable

Full address

Postcode

Signature

On completion, print and sign in front of a witness

Date (DD MM YYYY)

If you need more space, provide a separate sheet with details.

Witness's acknowledgement

The witness must be on the list of authorised witnesses and have a connection to Australia or be a notary public. For more information, go to **ag.gov.au**

26 I *(full name of witness in block letters)*

of *(full address)*

Postcode

hereby assert that the applicant(s) are known to me or, if not known, I am satisfied as to their identity and did witness the signing of this instrument before me on this day.

Witness's signature

Date (DD MM YYYY)

Reset form