

Application for approval, amendment or renewal of an approved pathology practitioner (HW009)

When to use this form

This form must be used by pathology practitioners to apply for, amend or renew an existing approved pathology practitioner (APP) under section 23DC of the *Health Insurance Act 1973*.

Important information

If you are not the proprietor of an accredited pathology laboratory (APL) detailed on this form, you must have a current agreement, arrangement or contract with the proprietor of the APL.

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 APP 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.

Amending an existing APP can include linking an APL number to your APP record.

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.

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

Returning this form



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 APP **Go to 3**
- to renew an existing APP *Go to next question*
- to amend an existing APP *Go to next question*

Applicant's details

Read this before answering the following questions.

If you are amending an existing APP, complete question 2 and 3, then all relevant questions that need amending.

If you are renewing an existing APP, complete all questions.

- 2 APP number

- 3 Full name

Dr Mr Mrs Miss Ms Mx Other

Family name

First given name

- 4 Postal address

 Postcode

- 5 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.

- 6 Alternative contact person

You may nominate someone to answer administrative questions.

Dr Mr Mrs Miss Ms Mx Other

Contact person's full name

Position held

Daytime phone number (including area code)

Mobile phone number

Current medical practitioner registration details

- 7 Current registration details

Australian Health Practitioner Regulation Agency (Ahpra) registration number

Registration expiry date (DD MM YYYY)

Professional qualifications

- 8 Professional qualifications obtained

If a renewal application, only list qualifications that have not been provided in previous applications.

Qualification 1

Qualification

Institution

Year attained (YYYY)

Qualification 2

Qualification

Institution

Year attained (YYYY)

Qualification 3

Qualification

Institution

Year attained (YYYY)

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

If you are a new applicant and do not possess a post graduate qualification in pathology accepted by the National Specialist Qualifications Advisory Committee, you will be required to supply further information.



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Laboratory details

9 Read this before answering the following question.

The laboratory address is the address from which services are rendered by you or on your behalf. Do not provide PO Box addresses.

Give details of the APL(s) where you will be providing services. If the laboratory is yet to be approved, provide as many details as possible. You are only eligible for Medicare benefits at APL(s) where you have a current agreement, arrangement or contract between yourself and the proprietor.

APL 1

APL number (if known)

Your provider number at this APL

Full laboratory address

Laboratory name

Building name

Unit Suite Shop Floor number

Street number

Street name

Suburb/Town

State Postcode

Are you the proprietor of this APL?

No

Yes **Go to APL 2 (if applicable) or go to 10**

Do you have a current agreement, arrangement or contract between yourself and the proprietor?

No You are not eligible for Medicare benefits from this laboratory and will not be linked to it.

Go to APL 2 (if applicable) or go to 10

Yes **Go to APL 2 (if applicable) or go to 10**

APL 2

APL number (if known)

Your provider number at this APL

Full laboratory address

Laboratory name

Building name

Unit Suite Shop Floor number

Street number

Street name

Suburb/Town

State Postcode

Are you the proprietor of this APL?

No

Yes **Go to APL 3 (if applicable) or go to 10**

Do you have a current agreement, arrangement or contract between yourself and the proprietor?

No You are not eligible for Medicare benefits from this laboratory and will not be linked to it.

Go to APL 3 (if applicable) or go to 10

Yes **Go to APL 3 (if applicable) or go to 10**

APL 3

APL number (if known)

Your provider number at this APL

Full laboratory address
Laboratory name

Building name

Unit Suite Shop Floor number

Street number

Street name

Suburb/Town

State Postcode

Are you the proprietor of this APL?
No
Yes **Go to APL 4 (if applicable) or go to 10**

Do you have a current agreement, arrangement or contract between yourself and the proprietor?
No You are not eligible for Medicare benefits from this laboratory and will not be linked to it.
Go to APL 4 (if applicable) or go to 10
Yes **Go to APL 4 (if applicable) or go to 10**

APL 4

APL number (if known)

Your provider number at this APL

Full laboratory address
Laboratory name

Building name

Unit Suite Shop Floor number

Street number

Street name

Suburb/Town

State Postcode

Are you the proprietor of this APL?
No
Yes **Go to 10**

Do you have a current agreement, arrangement or contract between yourself and the proprietor?
No You are not eligible for Medicare benefits from this laboratory and will not be linked to it.
Yes

If you provide services at more than 4 laboratories, attach a separate sheet with details for each of those laboratory locations.

Schedule 1 – Approved Pathology Practitioner Undertaking

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

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 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.

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.

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.

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
 - (ii) a scientist, or
 - (iii) a person having special qualifications or skills relevant to the service being renderedand 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 Providers, Pathology and Diagnostic Imaging Section 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 Services Australia 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 Services Australia is or becomes inaccurate or incomplete, I undertake to provide the Agency with such further information as will correct the earlier information as soon as possible.
- (3) If information provided to Services Australia is inaccurate or incomplete I undertake to provide the Agency with such further information as it requests. The information will be provided in such reasonable form as the Agency requires.
- (4) I undertake to advise the Director, Medicare Providers, Pathology and Diagnostic Imaging Section 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 Providers, Pathology and Diagnostic Imaging Section, or
 - (b) an Assistant Secretary in the Provider Benefits Integrity Division of the Department of Health and Aged Caremakes 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 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*.

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 Providers, Pathology and Diagnostic Imaging Section that will enable such a notice to be given on my behalf.

9 Agreements, arrangements and contracts of employment with APA

- (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 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 me, 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 (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 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 me 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

Part 4 – Laboratory Services

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

Privacy notice

13 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

Ensure your signing of this instrument is witnessed.

14 I (full name in block letters)

a medical practitioner who is or wishes to become an approved pathology practitioner, of (full address)

Postcode

hereby give this undertaking recorded in this Schedule to the Minister.

I declare that:

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

I 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 124FB 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 request that:

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

I understand that:

- giving false or misleading information is a serious offence.

Medical practitioner's signature

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

15 I (full name of witness in block letters)

of (full address)

Postcode

hereby assert that the applicant is 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)