

APP undertaking – August 2005

Part 1 – Compliance with legislation

- 1.1 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 I undertake 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 I undertake not to take any action that would constitute a relevant offence as defined in subsection 124B(1) of the Act.
- 1.4 I acknowledge that failure to comply with the requirements of part 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 I undertake 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 – Personal supervision

- 2.1 I acknowledge that it is my obligation, subject to part 2.2 and 2.4, personally to supervise any person who renders any service on my behalf and undertake to accept personal responsibility for the rendering of that service under the following condition of personal supervision:
 - (i) subject to the following condition, I will usually be physically available in the laboratory while services are being provided at the laboratory;
 - (ii) I may, subject to paragraph (vi) 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;
 - (iii) I may, subject to paragraph (vi) 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;
 - (iv) I will personally keep a written log of any 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;

- (v) if I am to be absent from the laboratory for more than seven 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 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;
- (vi) if a service is being rendered on my behalf by a person who is not:
 - (a) a medical practitioner
 - (b) a scientist
 - (c) a person having special qualifications or skills relevant to the service being rendered

and no person in the above groups is physically present in the laboratory, then I must be physically present in the laboratory and closely supervise the rendering of the service;

- (vii) I accept responsibly for taking all reasonable steps to ensure that in regard to services rendered by me or on my behalf:
 - (a) all persons who render services are adequately trained
 - (b) 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
 - (c) the methods and procedures in operation in the laboratory for the purpose of rendering services are in accordance with proper and correct practices
 - (d) for services and tests rendered are accurately recorded and sent to the treating practitioner and, where applicable, a referring practitioners;
- (viii) if I perform, or there is performed 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.

- 2.2 Where services are to be rendered on my behalf in a category B laboratory as defined in the *Health Insurance (Accredited Pathology Laboratory – Approval) Principles 2002*, 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 as in force from time to time.
- 2.3 I acknowledge to the best of my ability that any act or omission by a person, when acting with my authority, whether express or implied, that would, had it been done by me, have resulted in a breach of this undertaking, constitutes a breach of this undertaking by me.
- 2.4 Parts 2.1(i) to 2.1(vi) and 2.2 of this undertaking do not apply where a laboratory is limited to services (and associated equipment for those services) as detailed in schedule 3.

Part 3 – Dealing with relevant person

- 3.1 Where I can reasonably be expected to know, I undertake to inform the Manager Diagnostic Accreditation if any of the following occur:
- (i) I become a relevant person;
 - (ii) I become in control of operations of a relevant person;
 - (iii) any person who derives, or can reasonable be expected to derive (whether directly or indirectly) financial benefit from the services I provide within a laboratory becomes a relevant person;
 - (iv) I become financially associated with a relevant person;
 - (v) 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.
- 3.2 Where I should reasonably know a person is a relevant person, I undertake not to employ that person or enter into a contract or understanding with that person.

Part 4 – Information to be accurate

- 4.1 I undertake to ensure that information provided to Medicare Australia for services performed by me or on my behalf, including information relating to claims for payment, is accurate and complete.
- 4.2 If I become aware that information which has been provided to Medicare Australia is or becomes inaccurate or incomplete, I undertake to provide Medicare Australia with such further information as will correct the earlier information as soon as possible.
- 4.3 If information provided to Medicare Australia is inaccurate or incomplete I undertake to provide Medicare Australia with such further information as Medicare Australia requests. The information will be provided in such reasonable form as Medicare Australia requires.
- 4.4 I undertake to advise the Manager Diagnostic Accreditation in writing of any change in information already provided for the purpose of approval as a pathology practitioner.

Part 5 – Quality assurance

- 5.1 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.
- 5.2 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 information and reports generated as part of the quality assurance program to an independent body.

Part 6 – Request and use of information

- 6.1 If the Manager Diagnostic Accreditation makes a written request, I undertake to provide any relevant information specified in the request relating to services provided by or on my behalf, including any matter arising out of this undertaking.
- 6.2 I acknowledge that information provided pursuant to this undertaking may be copied, disseminated or otherwise made available to officers and the independent body.

Part 7 – Notice to practitioners, patients or other persons

- 7.1 I undertake to notify in writing any practitioner, patient or other person requesting or relying on services provided by me or on my behalf if approval to perform those services has been revoked, varied or refused by the Minister.
- 7.2 A notice under part 7.1 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.
- 7.3 I undertake to provide a notice pursuant to part 7.1 within five working days of being notified that my services have been revoked, varied or refused.
- 7.4 In the event that I am unable to comply with part 7.1, I undertake to provide such assistance as requested by the Manager Diagnostic Accreditation that will enable such a notice to be given on my behalf.

Part 8 – Agreements, arrangements and contracts of employment with approved pathology authority

- 8.1 I undertake not to provide any service in a laboratory in the absence of an agreement, arrangement or contract of employment between the laboratory proprietor and me.
- 8.2 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.

Part 9 – Accounts for services rendered by employed APP

- 9.1 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 and the Medicare Benefits Schedule book.

Part 10 – No inducement to use services

- 10.1 I undertake not to accept a request for services by or on my behalf where any benefit or incentive (other than an item set out in Schedule 2) 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.
- 10.2 The obligation under Part 10.1 only arises where I ought reasonably to have known that such benefit or incentive has been supplied.

Part 11 – Time and method of complying with undertakings

- 11.1 Where an obligation is placed upon me by this undertaking, I undertake 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.
- 11.2 Where an obligation is placed upon me by this undertaking that requires me to give information to the Manager Pathology, the information must be:
- (i) in writing or by email;
 - (ii) if in writing signed by me or by a person authorised in writing to sign on my behalf;
 - (iii) delivered or posted to

**The Manager Diagnostic Accreditation
Medicare Australia
PO Box 1001
Tuggeranong ACT 2901**

or such other address specified by notice in writing to me;

- (iv) if I am to use email to give such a notice, I undertake to take adequate steps to ensure that only myself, and person authorised in writing, have access to the email function on my computers and such notices shall be addressed to pathology.section@medicareaustralia.gov.au
- 11.3 I acknowledge that Section 163 of the *Evidence Act 1995 (Cth)* will apply to any document posted to me by Medicare Australia at the address nominated in support of which this undertaking is given or at such other address as may later be provided by me in writing to Medicare Australia.

Part 12 – Definitions

- 12.1 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;

‘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 person ordinarily qualified to witness a statutory declaration;

‘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;

‘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;

‘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:

- (i) has been given a notice,
- (ii) received a determination,
- (iii) been convicted of a relevant offence, or
- (iv) 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;

'Workday' means, in respect of a laboratory, a calendar day during which the laboratory provides pathology services;

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 (eg 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 (eg night boxes)—must be labelled as property of laboratory;
 Pathology download software specifically to retrieve pathology results for the laboratory. Pathology download software which is part of a larger suite should not be provided where:
 - additional functionality cannot be separated from the software,
 - a written licence agreement at normal commercial rates must exist between the APA and 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.

Schedule 3: laboratory services – parts 2.1(i) to (vi) and 2.2 do not apply

- Blood gas analysis
- Haemoglobin ometer
- Glucose reading

These services will be updated from time to time in consultation with the Royal College of Pathologists Australasia.

Commonwealth of Australia

Health Insurance Act 1973

APPROVED PATHOLOGY PRACTITIONER UNDERTAKING

For the purposes of section 23DC of the Health insurance Act 1973

I _____
(full name in block letters)

a medical practitioner who is or wishes to become an approved pathology practitioner, hereby give this undertaking recorded in pages 11 to 20 of this instrument to the Minister. I acknowledge that a breach of this undertaking may be referred to a Medicare Participation Review Committee (MPRC) in accordance with the Act and, pursuant to section 124FB of the Act, the MPRC may make a number of determinations including that Medicare payments should not be payable for up to five years.

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

Please ensure your signing of this instrument is witnessed

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