Health Insurance (Approved Pathology Undertakings) Approval 2002

HS/12/2002

I, KAY CHRISTINE LESLEY PATTERSON, Minister for Health and Ageing, make the following Approval under subsection 23DB(1) of the *Health Insurance Act 1973*.

Dated 13th November 2002

Kay Patterson

Minister for Health and Ageing

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1 Name of Approval

This Approval is the Health Insurance (Approved Pathology Undertakings) Approval 2002.

2 Commencement

This Approval commences on 1 January 2003.

3 Revocations

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

4 Approval of forms of undertaking (Act s 23DB(1))

(1) The form contained in Schedule 1 is the approved form of undertaking to be given by persons who wish to become approved pathology practitioners.

(2) The form contained in Schedule 2 is the approved form of undertaking to be given by persons who wish to become approved pathology authorities.

SCHEDULE 1

APPROVED PATHOLOGY PRACTITIONER UNDERTAKING

APP Undertaking

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

1.5 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 Parts 2.2 and 2.4, 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:

(i) Subject to the following conditions, 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 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;

(v) 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;

(vi) if a service is being rendered on my behalf by a person who is not:

(a) a medical practitioner;
(b) a scientist, or
(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 responsibility 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 rendered, proper quality control methods are established and reviewed to ensure their reliability and effectiveness; and
(e) results of services and tests rendered are accurately recorded and sent to the treating practitioner and, where applicable, a referring practitioner;

(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 Laboratories – 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 – Dealings with relevant person

3.1 Where I can reasonably be expected to know, I undertake to inform the Manager Pathology if any of the following circumstances 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 reasonably 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 HIC 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 HIC is or becomes inaccurate or incomplete, I undertake to provide HIC with such further information as will correct the earlier information as soon as possible.

4.3 If information provided to HIC is inaccurate or incomplete I undertake to provide HIC with such further information as HIC requests. The information will be provided in such reasonable form as HIC requires.

4.4 I undertake to advise the Manager Pathology 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 Pathology 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 5 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 Pathology 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 Pathology

Health Insurance Commission

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 persons authorised in writing, have access to the Email function on my computers and such notices shall be addressed to *pathology.section@hic.gov.au*

11.3 I acknowledge that Section 163 of the *Evidence Act 1995 (Cth)* will apply to any document posted to me by HIC 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 HIC.

Part 12 – Definitions

12.1 In this undertaking:

Words have, unless they are otherwise defined, the same meaning as in 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 as a true and accurate reproduction of the original. A referee may include persons such as – a member of the Institute of Chartered Accounts, Certified Practising Accountant, Barrister, Solicitor, legal practitioner, medical practitioner, justice of the peace and other persons ordinarily qualified to witness a statutory declaration;

"HIC" means the Health Insurance Commission or a member of staff of the Health Insurance Commission engaged pursuant to subsection 28(1) of the *Health Insurance Commission Act 1973*;

"Independent body" has the same meaning as in *the Health Insurance (Accredited Laboratories – Approval) Principles 2002*, or any legislation made in substitution for those Principles;

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

"Manager Pathology" means the person for the time being holding, acting in, or performing the duties of the position titled Manager Pathology within the Health Insurance Commission;

"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 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;

"Officer" means

(i) an officer of the Commonwealth Department of Health and Ageing, or

(ii) a member of the Health Insurance Commission, or

(iii) a member of the staff of the Health Insurance Commission 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: has been given a notice; received a determination; been convicted of a relevant offence; or, whom the Minister, on reasonable grounds, believes may have committed a relevant offence;

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

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

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

"Service" means pathology service(s) to which an item in the Medical 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 the Health Insurance Commission established pursuant to the *Electronic Transactions Act 1999.*

Schedule 1: Legislation

Health Insurance Act 1973
Health Insurance Regulations 1975
Health Insurance Commission Act 1973
Health Insurance Commission Regulations 1975
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 Centres) Approval Principles 2002
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) needles;
  Syringes 5mls or larger;
  Needles 21, 23 gauge;
  Alcowipes (or similar individual alcohol wipes);
  Spreaders for blood films;
  Small test tube racks;

- **Cervical cytology collection materials**
  Spray fixative;
  Cervix spatulas;
  Cyto brush;
  Direct to vial kits;
  Slides and slide carriers/holders;

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

- **Microbiological specimens**
  All microbiological or virology swabs and transport media;
  Urine containers;
  Faeces containers;
  Paediatric urine collection kits;
  Chlamydia specific collection and transport receptacles;
  TB specific collection receptacles;
  Blood culture bottles;
  Petri dishes;

Specimen biohazard bags/rubber bands;

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

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

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

- **Other**
  Fridge, where refrigeration is vital for the preservation of specimens (ie Laboratory being a long distance from collection point). Fridge 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 Down Load Software specifically to retrieve pathology results for the laboratory. Pathology download software which is part of a larger suite should not be provided – where additional functionality cannot be separated from the software, a written licence agreement at normal commercial rates must exist between the APA and referring practitioner or, agreement must be established in writing prohibiting use of non-pathology software reporting components.

These are the only items/services an APP/APA may supply free of charge, discounted or on a non-commercial basis, to a practitioner that requests or, intends to request, pathology services. This list may be updated from time to time in consultation with the Royal College of Pathologists Australasia.

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

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 5 to 15 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 5 years.

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

Signature: _____

Date: _____

Address:

No.		
Street Name		
Suburb	**State**	**Postcode**

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

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

Signature: _____

Date: _____

Address:

No.		
Street Name		
Suburb	**State**	**Postcode**

SCHEDULE 2

APPROVED PATHOLOGY AUTHORITY UNDERTAKING

APA Undertaking

Part 1 – Compliance with legislation

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

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

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

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

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

1.6 I am aware that if the Minister grants the application in support of which this undertaking is given the undertaking may outlast the period for which the Minister's approval is given.

Part 2 – Persons Acting on behalf of the Authority

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

(i) acts on behalf of the Authority; or

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

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

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

2.2 The Authority undertakes to remain accountable for any act by another APA, where such APA is a wholly owned subsidiary company or parent company of the Authority, that may result in a breach of the parent company or subsidiary company APA undertaking.

Part 3 – Financial affairs

3.1 The Authority undertakes to inform the Manager Pathology if any of the following circumstances occur:

(i) a matter relating to the financial affairs of the Authority is of such a nature that it has affected, or is likely to affect, the capability of the Authority to conduct the approved premises in the manner required by the legislation;

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

3.2 Where the Authority provides the Manager Pathology with information referred to in Part 3.1, the Authority undertakes to include with that information a statement setting out the steps that the Authority has undertaken or proposes to undertake to deal with the matters to which the information relates.

3.3 The Authority undertakes to inform the Manager Pathology if it is wound up or made bankrupt or if a trustee, liquidator, receiver, manager, administrator or court appointed agent is appointed to control the affairs of the Authority.

Part 4 – Dealings with relevant person

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

(i) the Authority becomes a relevant person;

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

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

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

(v) a director, secretary or officer of the Authority becomes a relevant person.

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

Part 5 – Information to be accurate

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

5.2 The Authority undertakes to advise the Manager Pathology in writing within 14 days of any change in any of the particulars contained in applications provided for the purpose of approval as an APA, APL and ACC.

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

5.4 The Authority undertakes to provide HIC 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 HIC in writing within 14 days of such request.

Part 6 – Inspection of Premises

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

(i) enter and inspect the premises;

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

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

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

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

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

6.3 An inspection as described in Part 6.1 may be undertaken without notice and at other times if the Minister or Managing Director certifies in writing that the inspection is necessary in the interests of public safety.

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

Part 7 – Cooperation with independent body

7.1 The Authority undertakes, at a time and date agreed to by the Authority and independent body, to permit a person or persons authorised by an independent body, and on production of such authorisation, to:

(i) enter and inspect the premises;

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

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

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

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

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

7.3 If an independent body recommends that the Authority undertake any remedial activities as a result of an inspection, the Authority undertakes to use its best endeavours to comply with that recommendation within any time period stated by the independent body. The Authority also undertakes to inform the independent body of the action that has been taken to give effect to the recommendation.

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

7.5 The Authority undertakes to comply with any directions of the Manager Pathology for the purposes of giving effect to the recommendation of the independent body.

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

Part 8 – Quality assurance

8.1 On request of an independent body, the Authority undertakes to provide the independent body with copies of all quality assurance program reports and related information relating to the Authority and any of its employees.

8.2 Where the Authority participates in a quality assurance program for the 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.

Part 9 – Notice of Matters Affection Approval of Premises

9.1 The Authority undertakes to notify the Manager Pathology if any of the following circumstances occur:

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

(ii) where the approved premises comprise or include a laboratory that was a State accredited laboratory when the Minister approved it as an accredited pathology laboratory under subsection 23DN(1) of the Act, the laboratory ceases to be a State accredited laboratory;

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

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

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

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

(vii) there is a change in the Approved Pathology Practitioners, or senior scientist responsible for any services performed in the premises, employed by the Authority;

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

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

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

Part 10 – Notice to practitioners, patients or other persons

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

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

10.3 The Authority undertakes to provide a notice pursuant to Part 10.1 within 5 working days of being notified that services have been revoked, varied or refused.

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

Part 11 – Request and use of information

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

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

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

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

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

Part 13 – No inducement to use services

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

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

Part 14 – Accounts for services rendered by employed APP

14.1 The Authority undertakes to ensure that where a service has been rendered by or on behalf of an APP employed by the Authority, an account for fees in relation to that service will be raised by the Authority on behalf of that APP. Such account will include, and be supported by, information and particulars required by the Act and the Medicare Benefits Schedule Book.

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

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

15.2 Where the Authority is part of a corporate structure comprising parent and subsidiary companies and, such subsidiaries are 100% owned by a parent company; the Authority undertakes to , as far as is possible, consolidate the corporate structure such that only one approval as a pathology authority is available to that corporate structure.

Part 16 – Time and method of complying with undertakings

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

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

(i) in writing or by Email;

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

(iii) delivered or posted to
The Manager Pathology
Health Insurance Commission
PO Box 1001
Tuggeranong, ACT, 2901

Or such other address as the HIC has specified by notice in writing to the Authority;

(iv) if the Authority uses Email to give such a notice the Authority undertakes to take adequate steps to ensure that only authorised persons have access to the Email function on computers of the Authority and such notices shall be addressed to *pathology.section@hic.gov.au*.

16.3 The Authority acknowledges that Section 163 of the *Evidence Act 1995 (Cth)* will apply to any document posted to the Authority by HIC 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 HIC.

Part 17 – Definitions

17.1 In this undertaking:

Words have, unless they are otherwise defined, the same meaning as in 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;

"Approved Premises" means any premises approved for the purpose of section 23DN (a laboratory) or section 23DNBA (a collection centre) of the Act;

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

"Certified" means a copy of a document where the copy has been authenticated by a referee as a true and accurate reproduction of the original. A referee may include persons such as – a member of the Institute of Chartered Accounts, Certified Practising Accountant, Barrister, Solicitor, a legal practitioner, a medical practitioner, justice of the peace and other persons ordinarily qualified to witness a statutory declaration;

"Entity" means a legal entity;

"HIC" means the Health Insurance Commission or a member of staff of the Health Insurance Commission engaged pursuant to subsection 28(1) of the *Health Insurance Commission 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;

"Managing Director" means the person for the time being holding the position titled Managing Director within the Health Insurance Commission and includes an officer holding a valid delegation to make a particular decision in place of the Managing Director;

"Manager Pathology" means the person for the time being holding, acting in, or performing the duties of the position titled Manager Pathology within the Health Insurance Commission;

"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 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;

"Officer" 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 the Health Insurance Commission, or

(iii) a member of the staff of the Health Insurance Commission who is engaged pursuant to subsection 28(1) of the Act;

"Premises" means the premises of the Authority signing this undertaking and shall include laboratory premises, administrative premises, collection centre premises and any other place

where the authority conducts business for the purpose of providing a pathology service pursuant to the Act;

“Principal shareholder” means, in relation to a company, the ten persons or bodies holding the greatest number of shares;

“Proprietor” means, in relation to premises, owner, lessee or other person having a right to possession;

“Quality assurance program” means a program offered for the purpose of testing proficiency in the testing of pathology specimens;

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

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

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

“Service” means pathology service(s) to which an item in the Medical 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;

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 the Health Insurance Commission established pursuant to the *Electronic Transactions Act 1999*.

Schedule 1: Legislation

Health Insurance Act 1973
Health Insurance Regulations 1975
Health Insurance Commission Act 1973
Health Insurance Commission Regulations 1975
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 Centres) Approval Principles 2002
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) needles;
  Syringes 5mls or larger;
  Needles 21, 23 gauge;
  Alcowipes (or similar individual alcohol wipes);
  Spreaders for blood films;
  Small test tube racks;

- **Cervical cytology collection materials**
  Spray fixative;
  Cervix spatulas;
  Cyto brush;
  Direct to vial kits;
  Slides and slide carriers/holders;

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

- **Microbiological specimens**
  All microbiological or virology swabs and transport media;
  Urine containers;
  Faeces containers;
  Paediatric urine collection kits;
  Chlamydia specific collection and transport receptacles;
  TB specific collection receptacles;
  Blood culture bottles;

Petri dishes;
Specimen biohazard bags/rubber bands;

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

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

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

- **Other**
  Fridge, where refrigeration is vital for the preservation of specimens (ie Laboratory being a long distance from collection point). Fridge 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 Down Load Software specifically to retrieve pathology results for the laboratory. Pathology download software which is part of a larger suite should not be provided – where additional functionality cannot be separated from the software, a written licence agreement at normal commercial rates must exist between the APA and referring practitioner or, agreement must be established in writing prohibiting use of non-pathology software reporting components.

These are the only items/services an APP/APA may supply free of charge, discounted or on a non-commercial basis, to a practitioner that requests or, intends to request, pathology services. This list may be updated from time to time in consultation with the Royal College of Pathologists Australasia.

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

Commonwealth of Australia

HEALTH INSURANCE ACT 1973

APPROVED PATHOLOGY AUTHORITY UNDERTAKING
For the purposes of section 23DF of the ***Health Insurance Act 1973***

I/We* _____
(* *name of applicant – as detailed on page 1*)

apply to become an approved pathology authority and hereby give this undertaking recorded in pages 6 to 18 of this instrument to the Minister. I/we acknowledge that a breach of this undertaking may be referred to a Medicare Participation Review Committee (MPRC) in accordance with the Act and, pursuant to section 124FB of the Act, the MPRC may make a number of determinations including that Medicare payments should not be payable for up to 5 years.

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

Name:	_____	Name:	_____
Position:	_____	Position:	_____
Signature:	_____	Signature:	_____
Date:	_____	Date:	_____
Address:	**No.** **Street Name** **Suburb** **State** **Postcode**	Address:	**No.** **Street Name** **Suburb** **State** **Postcode**

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

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

Signature: _____

Date: _____

Address:

No.

Street Name

Suburb **State** **Postcode**

Partnership

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

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

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

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

______________, ______________, ______________, ________.
(name in block letters) *(ABN if applicable)* *(signature)* *(date)*

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