

CATEGORY 6 - PATHOLOGY SERVICES

PART ONE - OUTLINE OF ARRANGEMENTS

PA. PATHOLOGY SERVICES IN RELATION TO MEDICARE BENEFITS

PA.1 Basic Requirements

PA.1.1 *Determination of Necessity of Service*

The treating practitioner must determine that the pathology service is necessary.

PA.1.2 *Request for Service*

The service may only be provided:

- (i) in response to a request from the treating practitioner or from another Approved Pathology Practitioner and the request must be in writing (or, if oral, confirmed in writing within fourteen days); or
- (ii) if determined to be necessary by an Approved Pathology Practitioner who is treating the patient.

PA.1.3 *Provision of Service*

The following conditions relate to provision of services:

- (i) the service has to be provided by or on behalf of an Approved Pathology Practitioner;
- (ii) the service has to be provided in a pathology laboratory accredited for that kind of service;
- (iii) the proprietor of the laboratory where the service is performed must be an Approved Pathology Authority;
- (iv) the Approved Pathology Practitioner providing the service must either be the proprietor of the laboratory or party to an agreement, either by way of contract of employment or otherwise, with the proprietor of the laboratory in which the service is provided; and
- (v) no benefit will be payable for services provided by an Approved Pathology Practitioner on behalf of an Approved Pathology Authority if they are not performed in the laboratories of that particular Approved Pathology Authority.

PA.1.4 *Therapeutic Goods Act 1989*

For any service listed in the MBS to be eligible for a Medicare rebate, the service must be rendered in accordance with the provisions of the relevant Commonwealth and State and Territory laws. Approved Pathology Practitioners have the responsibility to ensure that the supply of medicines or medical devices used in the provision of pathology services is strictly in accordance with the provisions of the *Therapeutic Goods Act 1989*.

PA.2 Exceptions to Basic Requirements

PA.2.1 *Prescribed Pathology Services*

A prescribed pathology service is a service included in Group P9 of the Pathology Services Table. Group P9 contains 11 services which may be performed by a medical practitioner in his or her own surgery on his or her own patients.

Additionally, benefit is payable only where the service is determined to be necessary by the medical practitioner rendering the service, or is in response to a request by a member of a group of practitioners to which that practitioner belongs (see PO.2 for the definition of a "group of practitioners").

PA.2.2 *Services Where Request Not Required*

A written request is not required for -

- (i) a prescribed pathology service rendered by or on behalf of a medical practitioner upon his or her own patients;
- (ii) a pathologist-determinable service. A pathologist-determinable service is a pathology service :

- (a) that is specified rendered by or on behalf of an Approved Pathology Provider for a person who is a patient of that Approved Pathology Provider who has determined that the service is necessary; or
- (b) that is specified in only one of immunohistochemistry items 72846, 72847 or 72848 or immunocytochemistry items 73059, 73060 or 73061 or electronmicroscopy items 72851 or 72852 and is considered necessary by the Approved Pathology Provider as a consequence of information resulting from a pathology service contained in tissue examination items 72813 – 72836, cytology items 73045 – 73051 or tissue examination items 72813 – 72836 respectively.
Please note: a written request is required for a service contained in items 72813 to 72836 and items 73045 to 73051.
- (c) That is specified in one of the antigen detection items 69364 or 69365 and is considered necessary by the specialist pathologist as a consequence of information provided by the requesting practitioner or by the nature or appearance of the specimen or as a consequence of information resulting from a pathology service contained in items 69303, 69306, 69312, 69318, 69321, 69345. Please note: a written request is required for a service contained in items 69303, 69306, 69312, 69318, 69321, 69345 or for a service contained in items 69364 or 69365.

Further information on additional pathology tests not covered by a request is provided at PB.3.

PA.3 Circumstances Where Medicare Benefits Not Attracted

PA.3.1 *Services Rendered by Disqualified Practitioner*

Medicare benefits are not payable for pathology services if at the time the service is rendered, the person, by or on whose behalf the service is rendered, is a person in relation to whom a determination is in force in relation to that class of services. That is, where an Approved Pathology Practitioner has breached an undertaking, and a determination has been made that Medicare benefits should not be paid during a specified period (of up to five years) in respect of specified pathology services rendered by the practitioner.

Note: An Approved Pathology Practitioner may be disqualified for reasons other than a breach of undertaking.

PA.3.2 *Certain Pathology Tests Do Not Attract Medicare Benefits*

Certain tests of public health significance do not qualify for payment of Medicare benefits. Examples of services in this category are:

- . examination by animal inoculation;
- . Guthrie test for phenylketonuria;
- . neonatal screening for hypothyroidism (T4/TSH estimation);
- . neonatal screening for Cystic Fibrosis;
- . neonatal screening for Galactosemia;
- . pathology services used with the intention of monitoring the performance enhancing effects of any substance;
- . pathology tests carried out on specimens collected from persons occupationally exposed to sexual transmission of disease where the purpose of the collection of specimens is for testing in accordance with conditions determined by the health authority of the State or Territory in which the service is performed.

In addition to the above, certain other tests do not qualify for payment of Medicare benefits. These include:

- . cytotoxic food testing;
- . pathology services performed for the purposes of tissue audit;
- . pathology services performed for the purposes of control estimation, repeat tests (eg. for confirmation of earlier tests on the same specimen, etc);
- . preparation of autogenous vaccines;
- . tissue banking and preparation procedures;
- . pathology services which are performed routinely in association with the termination of pregnancy without there being any indication for the necessity of the services. However, benefits will be paid for the following pathology tests: item 65060 - haemoglobin estimation;
item 65090 - blood grouping ABO and Rh (D antigen);
item 65096 - examination of serum for Rh and other blood group antibodies;
- . pathology services performed on stillborn babies or cadavers.

PB. REQUESTS

PB.1 Responsibilities of Treating/Requesting Practitioners

PB.1.1 Form of Request

A treating practitioner may request a pathology service either orally or in writing but oral requests must be confirmed in writing within fourteen days from the day when the oral request was made.

Pathology request forms and combined pathology request/offer to assign forms which are prepared by the pathologists and distributed to requesting practitioners must be approved by Medicare Australia (see PB.2). Written pathology requests from treating practitioners that are not on a form prepared and distributed by a pathologist do not need to be approved. However, all written requests for pathology services should contain the following particulars:

- (i) the individual pathology services, or recognised groups of pathology tests to be rendered (see section PQ of these notes for the list of acceptable terms and abbreviations). The description must be sufficient to enable the item in which the service is specified to be identified;
- (ii) the requesting practitioner's signature and date of request;
- (iii) the surname, initials of given names, practice address and provider number of the requesting practitioner;
- (iv) the patient's name and address;
- (v) details of the hospital status of the patient, as follows (for benefit rate assessment). That is, whether the patient was or will be, at the time of the service and when the specimen is obtained:
 - (a) a private patient in a private hospital, or approved day hospital facility;
 - (b) a private patient in a recognised hospital;
 - (c) a Medicare (public) patient in a recognised hospital;
 - (d) an outpatient of a recognised hospital;
- (vi) details of the person to whom the request is directed. A pathology request can be directed to an Approved Pathology Practitioner or an Approved Pathology Authority. If the request is directed to an Approved Pathology Authority, the form must show the full name and address of the Approved Pathology Authority. If the request is directed to an Approved Pathology Practitioner, the form must show the surname, initials or given names and place of practice of the Approved Pathology Practitioner to whom the request is addressed.

PB.1.2 Offence Not to Confirm an Oral Request

A requesting practitioner who, without reasonable excuse, does not confirm in writing an oral request within fourteen days of making the oral request is guilty of an offence under the *Health Insurance Act 1973* punishable, upon conviction, by a fine not exceeding \$1000, and the request is deemed never to have been made.

PB.2 Responsibilities of Approved Pathology Practitioners

PB.2.1 Form of Request

There is no official "request in writing" form, and the requesting practitioner's own stationery, or pre-printed forms supplied by Approved Pathology Practitioners/Authorities are acceptable, provided there are no check lists or "tick-a-box" lists of individual tests or groups of pathology services on the forms. However, pre-printed request forms issued by Approved Pathology Practitioners/Authorities for use by requesting practitioners must be approved by Medicare Australia. Forms submitted for approval should be accompanied by other information or documentation such as that contained in notes for guidance, cover sheets, etc., provided to requesting practitioners.

PB.2.2 Offence to Provide Unapproved Request Forms

An Approved Pathology Practitioner or Approved Pathology Authority who, without reasonable excuse, provides (directly or indirectly) to practitioners request forms which are not approved by Medicare Australia, is guilty of an offence under the *Health Insurance Act 1973* punishable, upon conviction, by a fine not exceeding \$1000.

PB.2.3 *Request to Approved Pathology Authority*

It is acceptable for a request to be made to an Approved Pathology Authority who is the proprietor or one of the proprietors of a laboratory instead of making the request to the Approved Pathology Practitioner who renders the service or on whose behalf the service is rendered.

PB.2.4 *Holding, Retention, Recording and Production of Request Forms*

Approved Pathology Practitioners must hold a request in writing for all services requested by any other practitioner before billing patients. An Approved Pathology Practitioner is required to retain written requests/confirmation of requests for pathology services for 18 months from the day when the service was rendered. This also applies to requests which an Approved Pathology Practitioner receives of which only some tests are referred to another Approved Pathology Practitioner (the first Approved Pathology Practitioner would retain the request for 18 months). If all tests were referred, the second pathologist would retain the original request.

If the written request or written confirmation has been recorded on film or other magnetic medium approved by the Minister for Health and Ageing, for the purposes of storage and subsequent retrieval, the record so made shall be deemed to be a retention of the request or confirmation. The production or reproduction of such a record shall be deemed to be a production of the written request or written confirmation.

An Approved Pathology Practitioner is required to produce, on request from an officer of Medicare Australia, no later than the end of the day following the request from the officer, a written request or written confirmation retained pursuant to the above paragraphs. The officer is authorised to make and retain copies of or take and retain extracts from written requests or written confirmations.

PB.2.5 *Offences in Relation to Retaining and Producing Request Forms*

The following offences are punishable upon conviction by a fine not exceeding \$1000:

- (i) an Approved Pathology Practitioner who, without reasonable excuse, does not keep request forms for 18 months;
- (ii) an Approved Pathology Practitioner who, without reasonable excuse, does not produce a request form to an officer of Medicare Australia before the end of the day following the day of the officer's request.

PB.2.6 *Referral From An Approved Pathology Practitioner To Another Approved Pathology Practitioner*

Where an Approved Pathology Practitioner refers some or all services requested to another Approved Pathology Practitioner not associated with the same Approved Pathology Authority the following apply:

- (i) where all the services are referred, the first Approved Pathology Practitioner should forward the original request to the second Approved Pathology Practitioner, and the document bearing the patient's assignment voucher so that the second Approved Pathology Authority can direct-bill Medicare;
- (ii) where some of the services which are listed in different items in the Schedule are referred, the first Approved Pathology Practitioner must issue his/her own request in writing listing the tests to be performed, and when necessary, forward a photocopy of the patient's assignment voucher so that the second Approved Pathology Authority can direct-bill Medicare;

in addition to the details of the first Approved Pathology Practitioner, the second Approved Pathology Practitioner must show on the account/receipt/assignment form:

- (a) name and provider number of the original requesting practitioner; and
- (b) date of original request;
- (iii) under the item coning rules (which limit benefits for multiple services) only one Medicare benefit is payable for services included in coned items except for estimations covered by Rule 6 entitled "designated pathology services". The exemption allows payment of more than one Medicare benefit where various components of the one item number from the same request e.g. drug assays (items 66800 and 66812) are performed by two Approved Pathology Authorities.

Although the provisions concerning designated pathology services in Rule 6 permit similar services (e.g. hormone estimations) to be performed by 2 or more laboratories, with different Approved Pathology Authorities, the sum of the Medicare benefit payable for services provided by the laboratories concerned will not exceed the maximum amount payable under the item coning rules when a single laboratory performs all the estimations.

Notes:

- (i) the patient should be billed by each Approved Pathology Practitioner only for those services rendered by or on his/her behalf;
- (ii) photocopies of requests are not acceptable;
- (iii) in the case of "designated pathology services" (i.e. items 66713, 66737, 66809, 66818 and 69402 only) a patient episode initiation fee (PEI) is payable for the services provided by the laboratory which receives the original request and performs one or more of the estimations. However, no PEI is payable for services provided by the other laboratory which performs the remainder of the estimations. A "specimen referred fee" is payable instead. One Approved Pathology Practitioner cannot claim both a PEI and a "specimen referred fee" in relation to the same patient episode.

PB.2.7 Offence Not To Confirm An Oral Request

An Approved Pathology Practitioner who, without reasonable excuse, does not confirm in writing an oral request to another Approved Pathology Practitioner within fourteen days of making the oral request is guilty of an offence under the *Health Insurance Act 1973* punishable, upon conviction, by a fine not exceeding \$1000, and the request is deemed never to have been made.

PB.3 Pathology Tests Not Covered by Request

An Approved Pathology Practitioner, who has been requested to perform one or more pathology services, may consider it necessary, in the interest of the patient, that additional tests to those requested be carried out. The Approved Pathology Practitioner must discuss this need with the requesting practitioner, and if the requesting practitioner determines that additional tests are necessary, the Approved Pathology Practitioner must arrange with the requesting practitioner to forward an amended or second request for those services. The account will then be issued in the ordinary way and the additional services will attract benefits providing the Approved Pathology Practitioner is a recognised specialist pathologist.

PC. DETAILS REQUIRED ON ACCOUNTS, RECEIPTS OR ASSIGNMENT FORMS

PC.1 General

Medicare benefit is not payable in respect of a pathology service unless specified details are provided, by the practitioner rendering the service, on his or her account, receipt or assignment form.

PC.2 Approved Pathology Practitioners

In addition to holding a request in writing from the treating medical or dental practitioner or from another Approved Pathology Practitioner, the following additional details must be recorded on the account, receipt or assignment form of the Approved Pathology Practitioner providing the service:

- (i) the surname and initials of the Approved Pathology Practitioner who performed the service and either his/her practice address or the provider number for the address;
- (ii) the name of the person to whom the service was rendered;
- (iii) the date on which the service was rendered;
- (iv) the name of the requesting practitioner;
- (v) the date on which the request was made;
- (vi) the requesting practitioner's provider number;
- (vii) a description of the pathology service in words which are derived from the item description in the Schedule and are of sufficient detail to identify the specific test in the Schedule that was rendered.

Instead of such a full description, the abbreviations contained in the index and the group abbreviations listed at PQ.4 are acceptable alternatives (see PQ.1);

- (viii) where the Approved Pathology Practitioner determines or provides a pathology service on his/her own patient, the account must be endorsed "sd"; and
- (ix) provide collection centre identification number if the specimen was collected in a licensed collection centre (or approved pathology collection centre).

Where some services are referred from one Approved Pathology Practitioner to another Approved Pathology Practitioner, the request details to be shown on the second Approved Pathology Practitioner's account, receipt or assignment form must be identical to those of the original requesting practitioner including the date of request.

PC.3 Prescribed Pathology Services

For Prescribed Pathology Services (that is, pathology items in Group P9) the medical practitioner who renders the service must ensure his or her account, receipt or assignment form includes his or her name, address or provider number, the date of the service, and a description to clearly identify the service in the Schedule that was rendered.

If the service was determined necessary by another medical practitioner who is a member of the same group practice as the practitioner who rendered the service, the name of the requesting practitioner, sufficient to identify the practitioner from other practitioners in the same group practice with the same surname, must also be included together with the date on which the request was made.

PD. MULTIPLE SERVICES RULE

PD.1 Description of Rule

The term "Multiple Services Rule" (Rule 3 of the Pathology Services Table) describes an arrangement which places limits on the benefits payable for items in the Pathology Services Table depending on the range of services performed during a single patient episode. A patient episode is defined in PO.4 of these notes.

PD.2 Exemptions

Under Rule 4 of the Pathology Services Table, exemptions to the multiple services rule have been granted for certain specified tests. In some circumstances tests which are repeated up to 6 times over a 24 hour period, or tests which are requested up to 6 times on a single request form and are performed within 6 months of the date of request may be eligible for separate Medicare benefits. The services to which the exemptions apply are listed under Rule 4.(1 and 2) and cover seriously or chronically ill patients who require particular tests under specified circumstances. In order to claim the exemptions, accounts should be endorsed "Rule 3 Exemption".

Where a practitioner seeks an exemption to the multiple services rule for a patient whose condition requires a series of pathology investigations at various times throughout any one day or over a longer period of time, and the services required are not exempted under Rule 4, an application for exemption can be made which is endorsed "S4B(3)". Some factors that the delegate of the Minister may take into consideration in approving an exemption are: the patient is seriously ill; there are distinct and separate collections and performances of tests; and the services involve substantial additional expenses for the Approved Pathology Practitioner. These, and other clinical details, should be supplied by the practitioner when seeking an S4B(3) exemption.

If Rule 3 exemptions are endorsed "S4B(3)", claim assessment could take longer as all S4B(3) claims are passed to the delegate for assessment. S4B(3) covers all exemptions to the multiple services rule but, where applicable, specific "Rule 3 exemption" endorsements will speed up the payment of claims. Rule 3 and S4B(3) exemptions cannot be used to overcome time based restrictions within items e.g. ".... each test to a maximum of 4 tests in a 12 month period".

PE. EPISODE CONE

PE.1 Description of Rule 18

The term "Episode Cone" describes an arrangement under which Medicare benefits payable in a patient episode for a set of pathology services, containing more than three items, ordered by a general practitioner for a non-hospitalised patient, will be equivalent to the sum of the benefits for the three items with the highest Schedule fees. Further information on the episode coning arrangements is provided in PO.5 of these notes.

PE.2 Exemptions

Some items are not included in the count of the items performed when applying episode coning. The items which have been exempted from the cone include all the items in Groups P10, P11 and P12, the Pap smear testing items (73053 and 73055), the designated pathology services items (66713, 66737, 66809, 66818 and 69402) and the supplementary test for Hepatitis B surface antigen or Hepatitis C antibody (69484).

PF. SCHEDULE FEES

PF.1 Single Level Fees

A single level Schedule fee as opposed to the previous SP and OP fee levels was introduced from 1 February 1992. The Schedule fee was set at 70% of the previous SP fee for all services except for a cytology item, a histopathology item and three high volume test items.

PF.2 Patient Episode Initiation Fees (PEIs)

Items in Groups P10 of the Pathology Services Table are only applicable to services performed:

- (i) by or on behalf of an Approved Pathology Practitioner who is a recognised specialist pathologist; and
- (ii) in private practice.

Accordingly, these fees are not payable for pathology services rendered by an Approved Pathology Practitioner, being a specialist pathologist when requested for a:

- (i) privately referred out-patient of a recognised hospital;
- (ii) private in-patient in a recognised hospital; or where
 - (a) any pathology equipment of a recognised hospital, or a laboratory included in a prescribed class of laboratories, is used; or
 - (b) any member of the staff of a recognised hospital, or a laboratory included in a prescribed class of laboratories, participates in the provision of the service in the course of his/her employment with that hospital or laboratory.

The patient episode initiation fees (PEIs) will be applicable on an episodic basis i.e. a claim may be made for the provision of pathology services requested by a practitioner in respect of one individual on the same day. For example, if a practitioner orders three pathology tests for a person on the one day, Medicare benefits will be payable for each of those tests but only one PEI will be applicable.

This Rule applies even when the treating practitioner has requested pathology tests from two or more Approved Pathology Practitioners. Thus a PEI will only be paid for the first account submitted unless an exemption listed in Rule 4 or 14.(7) applies or an exemption has been granted under "S4B(3)".

Under Rule 14.(7) two PEIs are payable in relation to the same patient episode where a referring practitioner refers two different specimens to two different Approved Pathology Authorities in the following circumstances:

- . a tissue pathology specimen and any other non-tissue pathology specimen; or
- . a cytopathology specimen and any other non-cytopathology specimen.

Rule 14.(8) also provides that only one PEI will be paid for the collection of specimens from a patient on one day in or by a single Approved Pathology Authority.

The patient episode initiation fees are two-tiered.

A higher fee will be payable for specimens collected in an approved collection centre, private hospital or day hospital facility where the patient is an in-patient. The specimen must be collected by an employee of the proprietor of the laboratory in which the pathology service will be rendered, or an Approved Pathology Practitioner associated with that laboratory.

A lower fee will be payable for specimens collected by the patient himself or herself or specimens collected by or on behalf of a treating practitioner.

PF.3 Patient Episode Initiation Fees for Certain Tissue Pathology and Cytology Items

Tissue Pathology items 72813, 72816, 72817, 72818, 72823, 72824, 72825, 72826, 72830 and 72836 and Cytology items 73053, 73055 and 73057 will be subject to a different patient episode initiation fee structure - items 73901 to 73905 refer.

PF.4 Hospital, Government etc Laboratories

The following laboratories have been prescribed for the purposes of payment of Medicare benefits as outlined in paragraphs PF.2 and PF.3:

- (i) laboratories operated by the Australian Government (these include health laboratories operated by the Australian Government Department of Health and Ageing as well as the laboratories operated by other Departments, e.g. the Departments of Defence and Veterans' Affairs operate laboratories from which pathology services are provided);
- (ii) laboratories operated by a State Government or authority of a State (laboratories operated or associated with recognised hospitals are also included);
- (iii) laboratories operated by the Northern Territory and the Australian Capital Territory; and
- (iv) laboratories operated by Australian tertiary education institutions eg Universities.

PG. ASSIGNMENT OF MEDICARE BENEFITS

PG.1 Patient Assignment

In addition to the general arrangements relating to the assignment of benefits, as outlined at paragraph 7 of the "General Explanatory Notes" in Section 1 of this book, it should be noted that, where the treating practitioner requests pathology services but the patient does not physically attend the Approved Pathology Practitioner, the patient may complete an assignment voucher at the time of the visit to the requesting doctor offering to assign benefits for the Approved Pathology Practitioner's services.

If an Approved Pathology Practitioner refers some of the tests requested by the treating practitioner to another Approved Pathology Authority, he/she should provide the second Approved Pathology Authority with a photocopy of the patient's assignment voucher so that the second Approved Pathology Authority can also direct-bill Medicare.

PG.2 Approved Pathology Practitioner Eligibility

If a practitioner requests an Approved Pathology Practitioner to perform a necessary pathology service, that Approved Pathology Practitioner must personally perform the service or have it performed on his/her behalf in order to be eligible to receive benefits by way of assignment. If, however, the first Approved Pathology Practitioner arranges for the service to be rendered by a second Approved Pathology Practitioner with the same Approved Pathology Authority, the second Approved Pathology Practitioner and not the first, is eligible to receive an assignment of the Medicare benefit for the service in question.

PH. ACCREDITED PATHOLOGY LABORATORIES

PH.1 Need For Accreditation

A pathology service will not attract Medicare benefits unless that service is provided in a pathology laboratory which is accredited for that kind of service. Details of the administration of the pathology laboratory accreditation arrangements are set out below.

PH.2 Applying For Accreditation

To become an Accredited Pathology Laboratory it is necessary to lodge a completed application form with the Manager, Pathology Section, Medicare Australia, PO Box 1001, TUGGERANONG ACT 2901. The prescribed fees for Approved Pathology Laboratories are:

- . \$2500 for Category GX labs
- . \$2000 for Category GY labs

- . \$1500 for Category B labs
- . \$ 750 for Category M & S labs.

It is necessary for an application for inspection be made to the National Association of Testing Authorities (NATA) NATA is the independent body chosen to act on the Australian Government's behalf as the primary inspection agency. The Royal Australian College of General Practitioners (RACGP) has also been appointed to inspect laboratories in Category M (general practitioner) in Victoria only.

Details of laboratory categories and associated supervisory requirements can be found on the Department's internet site (www.health.gov.au/pathology).

PH.3 Effective Period of Accreditation

Accreditation takes effect from the date of approval by the Minister for Health and Ageing. The Minister has no power to backdate an approval. Transitional accreditation may be given pending full accreditation. An application and fee are required annually.

PH.4 Assessment of Applications for Accreditation

The principles of accreditation for pathology laboratories as determined by the Minister are used to assess applications for accreditation. These principles also require pathology laboratories to address National Pathology Accreditation Advisory Council standards. Copies of the principles and standards are available from the Secretariat, National Pathology Accreditation Advisory Council (see PH.6) on (02) 6289 4017 or email npaac@health.gov.au.

PH.5 Refusal of Accreditation and Right of Review

An applicant who has been notified of the intention to refuse accreditation may, within 28 days of being notified, provide further information to the Minister which may be taken into consideration prior to a final decision being made.

Applicants refused accreditation or any person affected by the decision have the right to appeal to the Administrative Appeals Tribunal.

PH.6 National Pathology Accreditation Advisory Council (NPAAC)

NPAAC was established in 1979. Its functions are to develop policy for accreditation of pathology laboratories, introduce and maintain uniform standards of practice in pathology services throughout Australia and initiate and coordinate educational programs in relation to pathology practice. The agencies used to inspect laboratories on the Australian Government's behalf are required to conduct inspections using the standards set down by NPAAC. For further information the NPAAC Secretariat can be contacted on (02) 6289 4017 or email npaac@health.gov.au.

PH.7 Change of Address/Location

Laboratories are accredited for the particular premises given on the application form. Where a laboratory is relocated to other premises, any previously issued approvals for that Accredited Pathology Laboratory lapse. Medicare benefits are not payable for any pathology services performed at the new location until a new application has been approved by the Minister for Health and Ageing. Paragraph PH.2 sets out the method for applying for accreditation.

PH.8 Change of Ownership of a Laboratory

Part of the assessment of an application for an Accredited Pathology Laboratory relates to the Approved Pathology Authority status. Where the ownership, or some other material change occurs affecting the laboratory, the Minister for Health and Ageing must be provided with those changed details. Medicare benefits will not be payable for any pathology services performed on any premises other than those premises for which approval has been given.

PH.9 Approved Collection Centres (ACC)

New arrangements for specimen collection centres commenced on 1 December 2001 and replaced the Licensed Collection Centre (LCC) Scheme.

These arrangements were fully implemented on 1 July 2005 following a transition period of over four years to allow the pathology sector to adjust to a less regulated environment.

To enable the payment of Medicare benefits for pathology services performed on pathology specimens collected in a collection centre, the centre must first be approved. The exception to this rule is collection centres on the premises of recognised hospitals (recognised hospital in this context means the same as "recognized hospital" in Part 1 Section 3 of the Health Insurance Act 1973) as they do not need approval.

The number of collection centres an Approved Pathology Authority can operate under Medicare is primarily determined on the basis of its Medicare and Department of Veterans' Affairs pathology activity.

In order for a collection centre to be approved, a public or private Approved Pathology Authority must submit a completed application form to Medicare Australia including details of the type of application (renewal, new or cancellation of collection centre), the location of the premises, the owner, and any leasing arrangements.

Application forms can be accessed by going to Medicare Australia website www.medicareaustralia.gov.au. Completed application forms and any enquiries should be forwarded to the Manager, Pathology Section, Medicare Australia, PO Box 1001, TUGGERANONG ACT 2901.

PI. APPROVED PATHOLOGY PRACTITIONERS

PI.1 Introduction

A pathology service will not attract Medicare benefits unless that service is provided by or on behalf of an Approved Pathology Practitioner. (Approved Pathology Practitioners must be registered medical practitioners.) Set out below is information which relates to Approved Pathology Practitioner requirements.

PI.2 Applying for Acceptance of the Approved Pathology Practitioner Undertaking

To apply for acceptance of an Approved Pathology Practitioner Undertaking, it is necessary to send:

- (i) a completed application for acceptance of an Approved Pathology Practitioner Undertaking; and
- (ii) a signed Approved Pathology Practitioner Undertaking to the Pathology Registration Co-ordinator, Medicare Australia, PO Box 9822 (in your capital city).

An application form, undertaking and associated literature can be obtained from the Pathology Registration Co-ordinator.

PI.2.1 Payment of Acceptance Fee

On receipt of advice that the Minister has accepted an undertaking, a cheque for \$500 should be despatched to the Pathology Registration Co-ordinator. Applicants are required to pay this fee within 14 days of the notice being given (ie. the day the notice is sent).

As there is no discretion under the *Health Insurance Act 1973* to accept late payments, failure to pay the fee within the required time means that:

- (i) acceptance of the undertaking will be revoked;
- (ii) a new application must be completed;
- (iii) acceptance of the new undertaking cannot be backdated; and
- (iv) there will therefore be a period during which Medicare benefits cannot be paid.

PI.2.2 Reminder Process

In administering the Approved Pathology Authority and Approved Pathology Practitioner arrangements, Medicare Australia provides reminders to ensure that:

- (i) applicants whose undertaking are about to expire are aware of the consequences of late lodgement; and
- (ii) where the 14 day period for payment of fees is about to expire and the fees have not been paid, that applicants are aware of the consequences of failure to pay on time.

PI.3 Undertakings

PI.3.1 *Consideration of Undertakings*

The Minister is unable to accept an undertaking from a person in respect of whom there is a determination in force that the person has breached the undertaking, or from a person who, if the undertaking were accepted, would be likely to carry on the business of a prescribed person or would enable a person to avoid the financial consequences of the disqualification (or likely disqualification) of that prescribed person. A 'prescribed person' includes, amongst other things, fully or partially disqualified persons (or persons likely to be so disqualified).

Similarly an undertaking cannot be accepted unless the Minister is satisfied that the person giving such undertaking is a fit and proper person to be an Approved Pathology Practitioner.

When an undertaking has been given, the Minister may require the person giving the undertaking to provide additional information within a fixed period of time and if the person does not comply the Minister may refuse to accept the undertaking.

PI.3.2 *Refusal of Undertaking and Rights of Review*

Where the Minister refuses to accept an undertaking, for any of the reasons shown above, the Minister must notify the person of the decision. The notification must include advice of a right of internal review of the decision and a right of further appeal to the Administrative Appeals Tribunal if the internal review upholds the original decision to refuse the undertaking.

PI.3.3 *Effective Period of Undertaking*

The following applies:

- (i) Date of Effect - the earliest day from which the Minister or delegate can accept an undertaking is the day of the decision in respect of the undertaking. The day the undertaking is signed is to be the day it is actually signed and must not be backdated;
- (ii) Period of Effect - in determining the period of effect of the undertaking the Minister shall, unless the Minister considers that special circumstances exist, determine that the period of effect shall be twelve months from the day on which the undertaking comes into force. There is a requirement for the Minister to notify persons giving undertakings of the period of time for which the undertaking is to have effect, and the notice is to advise persons whose interests are affected by the decision of their rights of appeal to the Administrative Appeals Tribunal against the Minister's decision;
- (iii) Renewals - when an undertaking is given and accepted by the Minister while a former undertaking is current, the new undertaking does not take effect until the former undertaking ceases to be in force. When an undertaking is given while a former undertaking is current and the date on which the former undertaking is to expire passes without the Minister giving notice to accept or reject the new undertaking, the former undertaking remains in force until the Minister gives such notification. This provision does not apply when the renewal application is not received by Medicare Australia until after the expiry of the existing undertaking. Under these circumstances there will be a period during which Medicare benefits cannot be paid unless the new application can be backdated to the expiry of the previous undertaking. This is a limited discretion for periods up to one month and special conditions apply; and
- (iv) Cessation of Undertaking - the undertaking ceases to be in force if it is terminated, if the Minister revokes acceptance of the undertaking, or if the period of effect for the undertaking expires - whichever event first occurs.

An Approved Pathology Practitioner may terminate an undertaking at any time providing that the practitioner gives at least 30 days notice of his/her intention to do so.

PI.4 Obligations and Responsibilities of Approved Pathology Practitioners

The requirements of the legislation and the undertaking impose a number of obligations and responsibilities on Approved Pathology Practitioners and the Minister. The more complex of these not already dealt with are considered in PK, PL and PM dealing with Breaches of Undertakings, Excessive Pathology Services and Personal Supervision.

PJ. APPROVED PATHOLOGY AUTHORITIES

PJ.1 Introduction

A pathology service will not attract Medicare benefits unless the proprietor of the laboratory in which the pathology service is performed is an Approved Pathology Authority. Following is information which relates to Approved Pathology Authority requirements.

PJ.2 Applying for Acceptance of an Approved Pathology Authority Undertaking

To apply for acceptance of an Approved Pathology Authority Undertaking, it is necessary to send:

- (i) a completed application for acceptance of an Approved Pathology Authority Undertaking; and
- (ii) a signed Approved Pathology Authority Undertaking.

to the Manager Pathology Section, Health Insurance Section, PO Box 1001, Tuggeranong ACT 2901. Application forms, undertakings and associated literature can be obtained from the Pathology Registration Co-ordinator.

The application and the undertaking should be completed by the proprietor of the laboratory/ies and where the proprietor is not a natural person (e.g. company or partnership), an authorised representative/s should complete the forms. This proprietor can be:

- (i) a natural person;
- (ii) partners (natural persons and/or companies) in a partnership;
- (iii) a body corporate (i.e. a company); or
- (iv) a government authority (e.g. a public hospital).

PJ.2.1 *Payment of Acceptance Fee*

On receipt of advice that the Minister has accepted an undertaking, a cheque for \$1,500 should be dispatched within 14 days or the undertaking will be cancelled and the whole process begun again with a consequent gap in the payment of benefits.

PJ.3 Undertakings

PJ.3.1 *Consideration of Undertakings*

The Minister is unable to accept undertakings from a person in respect of whom there is a determination in force that the person has breached the undertaking, or from a person who, if the undertaking were accepted, would be likely to carry on the business of a prescribed person or would enable a person to avoid the financial consequences of the disqualification (or likely disqualification) of that prescribed person. A 'prescribed person' includes, inter alia, fully or partially disqualified persons (or persons likely to be so disqualified).

Similarly an undertaking cannot be accepted unless the Minister is satisfied that the person giving such undertaking is a fit and proper person to be an Approved Pathology Authority.

When an undertaking has been given the Minister may require the person giving the undertaking to provide additional information within a specified period of time and if the person does not comply the Minister may refuse to accept the undertaking.

PJ.3.2 *Refusal of Undertaking and Rights of Review*

Where the Minister refuses to accept an undertaking, the Minister must notify the person of the decision. The notification must include advice of a right of internal review of the decision and a right of further appeal to the Administrative Appeals Tribunal if the internal review upholds the original decision to refuse the undertaking.

PJ.3.3 *Effective Period of Undertaking*

The following applies:

- (i) Date of Effect - the earliest day from which the Minister or delegate can accept an undertaking is the day of the decision in respect of the undertaking. The day the undertaking is signed is to be the day it is actually signed and must not be backdated;
- (ii) Period of Effect - in determining the period of effect of the undertaking the Minister shall, unless the Minister considers that special circumstances exist, determine that the period of effect shall be twelve months from the day on which the undertaking comes into force. There is a requirement for the Minister to notify persons giving an undertaking of the period of time for which the undertaking is to have effect, and the notice is to advise persons whose interests are affected by the decision of their rights of appeal to the Administrative Appeals Tribunal against the Minister's decision;
- (iii) Renewals - when an undertaking is given and accepted by the Minister while a former undertaking is current, the new undertaking does not take effect until the former undertaking ceases to be in force. When an undertaking is given while a former undertaking is current and the date on which the former undertaking is to expire passes without the Minister giving notice to accept or reject the new undertaking, the former undertaking remains in force until the Minister gives such notification. This provision does not apply when the renewal application is not received by the Health Insurance Commission until after the expiry of the existing undertaking. Under these circumstances there will be a period during which Medicare benefits cannot be paid unless the new application can be backdated to the expiry of the previous undertaking. This is a limited discretion for periods up to one month and special conditions apply; and
- (iv) Cessation of Undertaking - the undertaking ceases to be in force if it is terminated, if the Minister revokes acceptance of the undertaking, or if the period of effect for the undertaking expires - whichever event first occurs.

An Approved Pathology Authority may terminate an undertaking at any time providing that at least 30 days notice of the intention to terminate the undertaking is given.

PJ.4 Obligations and Responsibilities of Approved Pathology Authorities

The requirements of the legislation and the undertaking impose a number of obligations and responsibilities on Approved Pathology Authorities and the Minister. The more complex of these which have not already been covered are considered in paragraphs PK and PL dealing with Breaches of Undertakings and Excessive Pathology Services.

PK. BREACHES OF UNDERTAKINGS

PK.1 Notice Required

Where the Minister has reasonable grounds for believing that an Approved Pathology Practitioner or an Approved Pathology Authority has breached the undertaking, the Minister is required to give notice in writing to the person explaining the grounds for that belief and inviting the person to put a submission to the Minister to show cause why no further action should be taken in the matter.

PK.2 Decisions by Minister

Where a person provides a submission, the Minister may decide to take no further action against the person. Alternatively the Minister may refer the matter to a Medicare Participation Review Committee, notifying the grounds for believing that the undertaking has been breached. If after 28 days no submission has been received from the person, the Minister must refer that matter to the Committee.

PK.3 Appeals

The Minister is empowered to suspend an undertaking where notice has been given to a Medicare Participation Review Committee of its possible breach, pending the outcome of the Committee's proceedings. The Minister must give notice in writing to the person who provided the undertaking of the determination to suspend it, and the notice shall inform the person of a right of appeal against the determination to the Administrative Appeals Tribunal. The Minister may also publish a notice of a determination in the Public Service Gazette. Rights of appeal to the Administrative Appeals Tribunal also exist in respect of any determination made by a Medicare Participation Review Committee.

PL. INITIATION OF EXCESSIVE PATHOLOGY SERVICES

PL.1 Notice Required

Where the Minister has reasonable grounds for believing that a person, of a specified class of persons, has initiated, or caused or permitted the initiation of excessive pathology services the Minister is required to give notice in writing to the person explaining the grounds for the belief and inviting the person to put a submission to the Minister to show cause why no further action should be taken in the matter.

PL.2 Classes of Persons

The classes of persons are:

- (i) the practitioner who initiated the services;
- (ii) the employer of the practitioner who caused or permitted the practitioner to initiate the services; or
- (iii) an officer of the body corporate employing the practitioner who caused or permitted the practitioner to initiate the services.

PL.3 Decisions by Minister for Health and Ageing

Where a person provides a submission, the Minister may decide to take no further action against the person. Alternatively, the Minister may refer the matter to a Professional Services Review (PSR) Committee, notifying the grounds for believing that excessive pathology services have been initiated. If after 28 days no submission has been received from the person, the Minister must refer the matter to the Committee. The Minister must give to the person notice in writing of the decision.

PL.4 Appeals

Unlike the procedures relating to breaches of undertaking there is no power given to the Minister to determine a penalty. The Minister's role is either deciding to take no further action or referring the matter to a PSR Committee. Accordingly, there are no rights of appeal to the Administrative Appeals Tribunal applicable to the above procedures. However, rights of appeal to the Administrative Appeals Tribunal exist in respect of any determination made by a Medicare Participation Review Committee.

PM. PERSONAL SUPERVISION

PM.1 Introduction

The *Health Insurance Act 1973* provides that the form of undertaking to be given by an Approved Pathology Practitioner may make provision for pathology services carried out under the personal supervision of the Approved Pathology Practitioner.

PM.2 Extract from Undertaking

The following is an extract from the Approved Pathology Practitioner (APP) undertaking:

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 personal 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.

PM.3 Notes on the Above

Part 2 of the APP Undertaking outlines the requirements for the personal supervision by an Approved Pathology Practitioner where a pathology service is rendered by another person on behalf of the APP. It should be noted that "on behalf of" does not relieve an Approved Pathology Practitioner of professional responsibility for the service or from being personally involved in the supervision of services in the laboratory.

PN. CHANGES TO THE PATHOLOGY SERVICES TABLE

PN.1 Health Insurance Regulations

The *Health Insurance Act 1973* allows the Minister for Health and Ageing to determine an appropriate Pathology Services Table which is then prescribed by Regulation.

The Minister has established the Pathology Services Table Committee (PSTC) to assist in determining changes to the Table (except new medical services and technologies - see below). Any person or organisation seeking to make a submission to this Committee can contact the PSTC Secretariat on (02) 6289 4081 or e-mail pstc@health.gov.au and/or write to: Secretary, PSTC, MDP 107, Department of Health and Ageing, GPO Box 9848, CANBERRA ACT 2601.

Pathology submissions relating to new medical services and technologies should be forwarded to the Medical Services Advisory Committee (MSAC). MSAC has been established to advise the Minister on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost effectiveness, and under what circumstances public funding should be supported.

Any person or organisation seeking to make a submission to MSAC can contact the MSAC Secretariat on (02) 6289 6811 or email msac.secretariat@health.gov.au and/or write to: Director, Strategic Policy Section, Department of Health and Ageing, GPO Box 9848, CANBERRA ACT 2601. The application form and guidelines for applying can also be obtained from MSAC's website – www.msac.gov.au

PART TWO - EXPLANATORY NOTES

PO. DEFINITIONS

PO.1 Excessive Pathology Service

This means a pathology service for which a Medicare benefit has become or may become payable and which is not reasonably necessary for the adequate medical or dental care of the patient concerned.

PO.2 Group of Practitioners

This means:

- (i) a practitioner conducting a medical practice or a dental practice together with another practitioner, or other practitioners, participating (whether as employees or otherwise) in the provision of professional services as part of that practice; or
- (ii) two or more practitioners conducting a medical practice or a dental practice as partners; or
- (iii) those partners together with any other practitioner who participates (whether as an employee or otherwise) in the provision of professional services as part of that practice.

PO.3 Initiate

In relation to a pathology service this means to request the provision of pathology services for a patient.

PO.4 Patient Episode

A patient episode comprises a pathology service or services specified in one or more items which are provided for a single patient, the need for which was determined under subsection 16A(1) of the Act on the same day, whether they were provided by one or more approved pathology practitioners on one day or over several days and whether they are requested by one or more treating practitioners. Even if a treating practitioner writes separate request forms to cover the collection of specimens at different times, where the decision to collect the multiple specimens was made at the same time, the multiple tests are deemed to belong to the same patient episode. In addition, if more than one request is made, on the same or different days, for tests on the same specimen within 14 days, they are part of the same patient episode.

Rule 4 of the Pathology Services Table provides an exemption to the above and enables services requested on one day which are performed under strictly limited circumstances for seriously or chronically ill patients with certain specified conditions to each be classified as a patient episode. See PD.2 for further information on exemptions.

Rule 14.(8) also provides that only a single patient episode initiation fee will be payable for all the specimens collected on one day from one patient in or by one Approved Pathology Authority.

PO.5 Episode Cone

The episode cone is an arrangement, described in Rule 18, which effectively places an upper limit on the number of items for which Medicare benefits are payable in a patient episode. This cone only applies to services requested by general practitioners for their non-hospitalised patients. Pathology services requested for hospital in-patients, or ordered by specialists, are not subject to these coning arrangements.

When more than 3 items are requested by a general practitioner in a patient episode, the benefits payable will be equivalent to the sum of the benefits for the three items with the highest Schedule fees. Rule 18 provides that for the two items with the highest Schedule fees, Medicare benefits will be payable for each item. The remaining items are regarded as one service for

which the benefit payable will be equivalent to that for the item with the third highest Schedule fee. Where items have the same Schedule fee, their item numbers are used as an artificial means to rank them.

The episode cone will apply even when the pathology services in a patient episode are performed by 2 or more Approved Pathology Authorities, with the exception of the services listed below.

The following items are not included in the count of the items performed when applying the episode cone:

- (i) all the items in Groups P10, P11 and P12;
- (ii) Pap smear testing (items 73053 and 73055);
- (iii) designated pathology services (items 66713, 66737, 66809, 66818 and 69402); and
- (iv) supplementary test for Hepatitis B and Hepatitis C (item 69484).

PO.6 Personal Supervision

This means that an Approved Pathology Practitioner will, to the fullest extent possible, be responsible for exercising an acceptable level of control over the rendering of pathology services. See PM.1 to PM.3 for a full description of the responsibilities involved in personal supervision.

PO.7 Prescribed Pathology Service

These are simple basic pathology services which are included in Group P9 and may be performed by a medical practitioner in the practitioner's surgery without the need to obtain Approved Pathology Authority, Approved Pathology Practitioner or Accredited Pathology Laboratory status.

PO.8 Proprietor of a Laboratory

This means in relation to a pathology laboratory the person, authority or body of persons having effective control of:

- (i) the laboratory premises, whether or not the holder of an estate or interest in the premises;
- (ii) the use of equipment used in the laboratory; and
- (iii) the employment of staff in the laboratory.

PO.9 Specialist Pathologist

This means a medical practitioner recognised for the purposes of the *Health Insurance Act 1973* as a specialist in pathology (see 5.1 of the "General Explanatory Notes" in Section 1 of this book). The principal specialty of pathology includes a number of sectional specialties. Accordingly, a medical practitioner who is recognised as a specialist in a sectional specialty of pathology is recognised as a specialist pathologist for this purpose.

PO.10 Designated Pathology Service

This means a pathology service specified in items 66713, 66737, 66809, 66818 and 69402. Where one Approved Pathology Practitioner in an Approved Pathology Authority has performed some but not all the estimations in a coned item and has requested another Approved Pathology Practitioner in another Approved Pathology Authority to do the rest, the service provided by the second practitioner is deemed to be the "designated pathology service". Thus the first practitioner claims under the appropriate item for the services which he/she provides while the second practitioner claims one of items 66713, 66737, 66809, 66818 or 69402. Where one Approved Pathology Practitioner in an Approved Pathology Authority has performed some, but not all estimations and has requested another Approved Pathology Practitioner in another Approved Pathology Authority to do the remainder, the first Approved Pathology Practitioner can raise a "patient episode initiation fee". The second Approved Pathology Practitioner who receives the specimen can raise a "specimen referred fee".

PP. INTERPRETATION OF THE SCHEDULE

PP.1 Faecal Occult Blood (Items 66764 - 66770)

The fee for items 66764-66770 is only payable where both test methods described in the item have been performed.

PP.2 Tissue Pathology and Cytology (Items 72813 - 73061)

When services described in Group P5 need to be performed upon material which is submitted for cytology items listed in Group P6 only the fee for the P6 item can be claimed.

PP.3 Cervical and Vaginal Cytology (Items 73053 - 73057)

Item 73053 applies to the cytological examination of cervical smears collected from women with no symptoms, signs or recent history suggestive of cervical neoplasia as part of routine, biennial examination for the detection of pre-cancerous or cancerous changes. This item also applies to smears repeated due to an unsatisfactory routine smear, or if there is inadequate information provided to use item 73055.

Cytological examinations carried out under item 73053 should be in accordance with the agreed National Policy on Screening for the Prevention of Cervical Cancer. This policy provides for:

- (i) an examination interval of two years for women who have no symptoms or history suggestive of abnormal cervical cytology, commencing between the ages of 18 to 20 years, or one to two years after first sexual intercourse, whichever is later; and
- (ii) cessation of cervical smears at 70 years for women who have had two normal results within the last five years. Women over 70 who have never been examined, or who request a cervical smear, should be examined.

This policy has been endorsed by the Royal Australian College of General Practitioners, the Royal Australian College of Obstetricians and Gynaecologists, The Royal College of Pathologists of Australasia, the Australian Cancer Society and the National Health and Medical Research Council.

The *Health Insurance Act 1973* excludes payment of Medicare benefits for health screening services except where Ministerial directions have been issued to enable benefits to be paid, such as the Papanicolaou test. As there is now an established policy which has the support of the relevant professional bodies, routine screening in accordance with the policy will be regarded as good medical practice.

The screening policy will not be used as a basis for determining eligibility for benefits. However, the policy will be used as a guide for reviewing practitioner profiles.

Item 73055 applies to cervical cytological examinations where the smear has been collected for the purpose of management, follow up or investigation of a previous abnormal cytology report, or collected from women with symptoms, signs or recent history suggestive of abnormal cervical cytology.

Items 73057 applies to all vaginal cytological examinations, whether for a routine examination or for the follow up or management of a previously detected abnormal smear.

For cervical smears, treating practitioners are asked to clearly identify on the request form to the pathologist, by item number, if the smear has been taken as a routine examination or for the management of a previously detected abnormality.

PP.4 Eosinophil Cationic Protein (Item 71095)

Item 71095 applies to children aged less than 12 years who cannot be reliably monitored by spirometry or flowmeter readings.

PP.5 Additional bulk billing payment for pathology services (item 74990 and 74991)

Item 74990 operates in the same way as item 10990 and item 74991 operates in the same way as item 10991 (see explanatory note M.1), apart from the following differences:

- Item 74990 and 74991 can only be used in conjunction with items in the Pathology Services Table of the MBS;
- Item 74990 and 74991 applies to unreferred pathology services performed by a medical practitioner which are included in Group P9 of the Pathology Services Table, and unreferred pathology services provided by category M laboratories;
- Item 74990 and item 74991 applies to pathology services self determined by general practitioners and specialists with dual qualifications acting in their capacity as general practitioners;
- Specialists and consultant physicians who provide pathology services are not able to claim item 74990 or item 74991 unless, for the purposes of the Health Insurance Act, the medical practitioner is also a general practitioner and the service provided by the medical practitioner has not been referred to that practitioner by another medical practitioner or person

with referring rights.

Rules 3 and 18 of the *Health Insurance (Pathology Services Table) Regulations 2003* have been amended to exclude item 74990 and 74991 from the Multiple Services Rule and the Coning Rule.

Item 74991 can only be used where the service is provided at, or from, a practice location in a regional, rural or remote area (RRMA 3 to 7 under the Rural Remote Metropolitan Areas classification system), or in all of Tasmania.

PP.6 Antibiotics/Antimicrobial Chemotherapeutic Agents

A test for the quantitation of antibiotics/antimicrobial chemotherapeutic agents is claimable under item 66800 or 66812 - 'quantitation of a drug being used therapeutically'.

PP.7 Items referring to the 'detection of'

Items that contain the term 'detection of' should be taken to mean 'testing for the presence of'.

PP.8 Blood Grouping (Item 65096)

Where a request includes 'Group and Hold' or 'Group and Save', the appropriate item is 65096.

PP.9 Iron Studies (Item 66596)

Where a request includes 'Iron Studies', 'IS', 'Fe', '% saturation' or 'Iron', the relevant item is 66596.

PP.10 Glycosylated haemoglobin (Item 66551)

The requirement of "established diabetes" in this item may be satisfied by:

- a) a statement of the diagnosis by the ordering practitioner on the current request form or on a previous request form held in the database of the Approved Pathology Authority; or
- b) two or more blood glucose levels that are in the diabetic range and is contained in the database of the Approved Pathology Authority; or
- c) an oral glucose tolerance test result that is in the diabetic range and is contained in the database of the Approved Pathology Authority.

PP.11 Hepatitis (Item 69481)

Benefits for item 69481 are payable only if the request from the ordering practitioner indicates in writing that the patient is suspected of suffering from acute or chronic hepatitis; either by the use of the provisional diagnosis of hepatitis or by relevant clinical or laboratory information eg "hepatomegaly", "jaundice" or "abnormal liver function tests".

PP.12 Fragile X (A) Tests (Items 73300 and 73305)

Prior to ordering these tests (73300 and 73305) the ordering practitioner should ensure the patient has given informed consent. Appropriate genetic counselling should be provided to the patient either by the treating practitioner, a genetic counselling service or by a clinical geneticist on referral. Further counselling may be necessary upon receipt of the test results.

PP.13 Human Immunodeficiency Virus (HIV) Diagnostic Tests (included in items 69384, 69387, 69390, 69393, 69396, 69399, 69402, 69405, 69408, 69411, 69413, 69415)

Prior to ordering an HIV diagnostics tests (included in items 69384, 69387, 69390, 69393, 69396, 69399, 69402, 69405, 69408, 69411, 69413, 69415) the ordering practitioner should ensure that the patient has given informed consent. Appropriate counselling should be provided to the patient. Further counselling may be necessary upon receipt of the test results.

PQ. ABBREVIATIONS, GROUPS OF TESTS

PQ.1 Abbreviations

As stated at PC.2 of the Outline, details that must be recorded on accounts, receipts or assignment forms of an Approved Pathology Practitioner/Authority include a description of the pathology service that is of sufficient detail to identify the specific service rendered. The lists of abbreviations for group tests are contained in PQ.4. The lists of abbreviations for

individual tests are contained in the Index to this Section. The abbreviations are provided to allow users to identify and refer to particular pathology services, or particular groups of pathology services, more accurately and conveniently.

The above requirements may be used for billing purposes but treating practitioners requesting pathology services are encouraged to use the approved abbreviations. In this regard treating practitioners should note that:

- . pathology services cannot be self determined by a rendering pathologist responding to a request. This places the onus for medical necessity on the treating practitioner who, in normal circumstances would, if he or she was unclear in deciding the appropriate test for a clinical situation, consult a pathologist for assistance; and
- . Approved Pathology Practitioners/Authorities undertake not to issue accounts etc unless the pathology service was rendered in response to an unambiguous request.

PQ.2 Tests not Listed

Tests which are not listed in the Pathology Services Table do not attract Medicare benefits. As explained at PN.1 of the Outline, changes to the Pathology Services Table can only be made by the Minister for Health and Ageing.

PQ.3 Audit of Claims

Medicare Australia is undertaking routine audits of claims for pathology benefits against requested services to ensure compliance with the provisions of the *Health Insurance Act 1973*.

PQ.4 Groups of Tests

For the purposes of recording a description of the pathology service on accounts etc, an Approved Pathology Practitioner /Authority may use group abbreviations or group descriptions for the following specified groups of tests. These groups consist of two or more tests within the same item. These groups exclude abbreviations such as MBA and TORCH.

Treating practitioners are encouraged to use these group abbreviations or group descriptions where appropriate.

For ease of identification of group tests, it is recommended that practitioners use the following abbreviations. Tests requested individually may attract Medicare benefits.

Group	Estimations Included in Group	Group Abbreviation	Item Numbers
Cardiac enzymes or cardiac markers	Creatine kinase isoenzymes, myoglobin, troponin	CE / CM	66518, 66519
Coagulation studies	Full blood count, Prothrombin time, activated partial thrombo- plastin time and two or more of the following tests- fibrinogen, thrombin clotting time, fibrinogen degradation products, fibrin monomer, D-dimer factor XIII screening tests	COAG	65129, 65070
Electrolytes	Sodium (NA) potassium (K) chloride (CL) and bicarbonate (HCO ₃)	E	66509
Full Blood Examination	Erythrocyte count Haematocrit Haemoglobin Platelet count Red cell count Leucocyte count Manual or instrument generated differential Morphological assessment of blood film where appropriate	FBE, FBC, CBC	65070

Lipid studies	Cholesterol (CHOL) and triglycerides (TRIG)	FATS	66503
Liver function tests	Alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), albumin (ALB), bilirubin (BIL), gamma glutamyl transpeptidase (GGT), lactate dehydrogenase (LDH), and protein (PROT).	LFT	66515
Syphilis serology	Rapid plasma reagin test (RPR), or venereal disease research laboratory test (VDRL), and treponema pallidum haemagglutinin test (TPHA), or fluorescent treponemal antibody-absorption test (FTA)	STS	69387
Urea, electrolytes, creatinine	Urea, electrolytes, creatinine	U&E	66515

PR. COMPLEXITY LEVELS FOR HISTOPATHOLOGY ITEMS

PR.1 Complexity Levels

Only one of these histopathology examination items (72813, 72816, 72817, 72818, 72823, 72824, 72825, 72826, 72830 and 72836) can be claimed in a patient episode.

The remaining items (72844, 72846, 72847, 72848, 72851, 72852, 72855, 72856 and 72857) are add-on items, covering enzyme histochemistry and immunohistochemistry, electron microscopy and frozen sections, which can be claimed in addition to the main item.

The list of complexity levels by type of specimen are contained at the back of this Section.

PX. PATHOLOGY SERVICES TABLE

PX.1 Rules for the Interpretation of the Pathology Services Table

1. (1) In this table

patient episode means:

- (a) a pathology service or pathology services (other than a pathology service to which paragraph 1 (1) (b) refers) provided for a single patient whose need for the service or services was determined under section 16A of the Act:

- (i) on the same day; or
 - (ii) if more than 1 test is performed on the 1 specimen within 14 days - on the same or different days;

whether the services:

- (iii) are requested by 1 or more practitioners; or
 - (iv) are described in a single item or in more than 1 item; or
 - (v) are rendered by 1 approved pathology practitioner or more than 1 approved pathology practitioner; or
 - (vi) are rendered on the same or different days; or

- (b) a pathology service to which rule 4 refers that is provided in the circumstances set out in that rule that relates to the service.

recognised pathologist means a medical practitioner recognised as a specialist in pathology by a determination under section 3D or subsection 61 (3) of the Act.

serial examinations means a series of examinations requested on 1 occasion whether or not:

- (a) the materials are received on different days by the approved pathology practitioner; or
- (b) the examinations or cultures were requested on 1 or more request forms by the treating practitioner.

the Act means the *Health Insurance Act 1973*.

- 1. (2) In these rules, a reference to a request to an approved pathology practitioner includes a reference to a request for a pathologist-determinable service to which subsection 16A (6) of the Act applies.
- 1. (3) A reference in this table by number to an item that is not included in this table is a reference to the item that has that number in the general medical services table or the diagnostic imaging services table, as the case requires.
- 1. (4) A reference to a **Group** in the table includes every item in the Group and a reference to a **Subgroup** in the table includes every item in the Subgroup.

Precedence of items

- 2. (1) If a service is described:
 - (a) in an item in general terms; and
 - (b) in another item in specific terms;only the item that describes the service in specific terms applies to the service.
- 2. (2) Subject to subrule (3), if:
 - (a) subrule (1) does not apply; and
 - (b) a service is described in 2 or more items;only the item that provides the lower or lowest fee for the service applies to the service.
- 2. (3) If an item is expressed to include a pathology service that is described in another item, the other item does not apply to the service in addition to the first-mentioned item, whether or not the services described in the 2 items are requested separately.

Application of item 74990 and 74991

- 2. (4) Despite subrules (1), (2) and (3):
 - (a) if the pathology service described in item 74991 is provided to a person, either that item or item 74990, but not both those items, applies to the service; and
 - (b) if item 74990 or 74991 applies to a pathology service, the fee specified in that item applies in addition to the fee specified in any other item in the table that applies to the service.
- 2. (5) For items 74990 and 74991:

bulk-billed, in relation to a pathology service, means:

 - (a) a medicare benefit is payable to a person in respect of the service; and
 - (b) under an agreement entered into under section 20A of the Act:
 - (i) the person assigns to the practitioner by whom, or on whose behalf, the service is provided, his or her right to the payment of the medicare benefit; and
 - (ii) the practitioner accepts the assignment in full payment of his or her fee for the service provided.

Commonwealth concession card holder means a person who is a concessional beneficiary within the meaning given by subsection 84 (1) of the *National Health Act 1953*.

unreferred service means a pathology service that:

- (a) is provided to a person by, or on behalf of, a medical practitioner, being a medical practitioner who is not a consultant physician, or specialist, in any speciality (other than a medical practitioner who is, for the purposes of the Act, both a general practitioner and a consultant physician, or specialist, in a particular speciality); and
- (b) has not been referred to the medical practitioner by another medical practitioner or person with referring rights.

2. (6) For item 74991:

ASGC means the document titled Australian Standard Geographical Classification (ASGC) 2002, published by the Australian Bureau of Statistics, as in force on 1 July 2002.

practice location, in relation to the provision of a pathology service, means the place of practice in respect of which the practitioner by whom, or on whose behalf, the service is provided, has been allocated a provider number by the Commission.

Regional, rural or remote area means an area classified as RRMA 3-7 under the Rural, Remote and Metropolitan Areas Classification.

Rural, Remote and Metropolitan Areas Classification has the meaning given by subrule 3 (1) of Part 2 of Schedule 1 to the general medical services table.

SLA means a Statistical Local Area specified in the ASGC.

SSD means a Statistical Subdivision specified in the ASGC.

Circumstances in which services rendered following 2 requests to be taken to have been rendered following 1 request

3. (1) In subrule 3(2), **service** includes assay, estimation and test.

3. (2) Two or more pathology services (other than services to which, under rule 4, this rule does not apply) rendered for a patient following 2 or more requests are taken to have been rendered following a single request if:

- (a) the services are listed in the same item; and
- (ab) that item is not item 74990 or 74991; and
- (b) the patient's need for the services was determined under subsection 16A (1) of the Act on the same day even if the services are rendered by an approved pathology practitioner on more than one day.

Services to which rule 3 does not apply

4. (1) Rule 3 does not apply to a pathology service described in item 65060, 65070, 65120, 65123, 65126, 65129, 65150, 65153, 65156, 66500, 66503, 66506, 66509, 66512, 66515, 66584 or 66800, if:

- (a) the service is rendered in relation to one or more specimens taken on each of not more than 6 separate occasions in a period of 24 hours; and
- (b) the service is rendered to an inpatient in a hospital; and
- (c) each service must be rendered as soon as possible after collection and after authorization of the result of the previous specimen; and
- (d) the account for the service is endorsed 'Rule 3 Exemption'.

4. (2) Rule 3 does not apply to any of the following pathology services:

- (a) estimation of prothrombin time (INR) in respect of a patient undergoing anticoagulant therapy;
- (b) quantitative estimation of lithium in respect of a patient undergoing lithium therapy;
- (c) a service described in item 65070 in relation to a patient undergoing chemotherapy for neoplastic disease or immunosuppressant therapy;
- (d) a service described in item 65070 in relation to clozaril, ticlopidine hydrochloride, methotrexate, gold, sulphasalazine or penicillamine therapy of a patient;
- (e) a service described in item 66500 - 66515 in relation to methotrexate or leflunomide therapy of a patient;
- (f) quantitative estimation of urea, creatinine and electrolytes in relation to:
 - (i) cis-platinum or cyclosporin therapy of a patient; or
 - (ii) chronic renal failure of a patient being treated in a dialysis program conducted by a recognised hospital;
- (g) quantitative estimation of albumin and calcium in relation to therapy of a patient with vitamin D, its metabolites or analogues;

if:

- (h) under a request for a service, other than a request for a service described in paragraph (a), no more than 6 tests are requested; and
- (i) the tests are performed within 6 months of the request; and
- (j) the account for the service is endorsed "Rule 3 Exemption".

Item taken to refer only to the first service of a particular kind

- 5. (1)** For an item in Group P1 (Haematology):
- (a) if pathology services of a kind referred to in item 65090 or 65093 are rendered for a patient during a period when the patient is in hospital, the item applies only to the first pathology service of that kind rendered for the patient during the period; and
 - (b) if:
 - (i) tests (except tests mentioned in item 65099, 65102, 65105 and 65108) are carried out in relation to a patient episode; and
 - (ii) specimen material from the patient episode is stored; and
 - (iii) in response to a request made within 14 days of the patient episode, further tests (except tests mentioned in item 65099, 65102, 65105 and 65108) are carried out on the stored material; the later tests and the earlier tests are taken to be part of one patient episode.

- 5. (2)** Benefits for items 65102 and 65108 are payable only if a minimum of 6 units are issued for the patient's care in any 1 day.

- 5.(3)** For items 65099 and 65102:

compatibility tests by crossmatch means that, in addition to all the tests described in paragraphs (a) and (b) of the item, donor red cells from each unit must have been tested directly against the serum of the patient by 1 or more accepted crossmatching techniques.

Certain items not to apply to a service referred by one pathology practitioner to another

- 6. (1)** In this rule:

designated pathology service means a pathology service in respect of tests relating to a single patient episode that are:

- (a) tests of the kind described in item 66695; or
- (b) tests of the kind described in item 66722; or
- (c) tests of the kind described in item 66800; or
- (d) tests of the kind described in item 66812; or
- (e) tests of the kind described in item 69384.

- 6. (2)** This rule applies in respect of a designated pathology service where:

- (a) an approved pathology practitioner (**practitioner A**) in an approved pathology authority:
 - (i) has been requested to render the designated pathology service; and
 - (ii) is unable, because of the lack of facilities in, or expertise or experience of the staff of, the laboratory of the authority, to render 1 or more (but not all) of the tests included in the service; and
 - (iii) requests an approved pathology practitioner (**practitioner B**) in another approved pathology authority to render the test or tests that practitioner A is unable to render; and
 - (iv) renders each test included in the service, other than the test or tests in respect of which the request mentioned in subparagraph (iii) is made: and
- (b) the tests mentioned in subparagraph (a) (iv) that practitioner A renders are not tests constituting a service described in item 66710, 66734, 66806, 66815 or 69399.

- 6. (3)** If this rule applies in respect of a designated pathology service:

- (a) item 66695, 66698, 66701, 66704, 66707, 66722, 66725, 66728, 66731, 66800, 66803, 66812, 69384, 69387, 69390, 69393 or 69396 (as the case requires) applies in respect of the test or tests rendered by practitioner A; and
- (b) where practitioner B renders a service under a request referred to in subparagraph (2) (a) (iii) - subject to subrule (4), the amount specified in item 66713, 66737, 66809, 66818, or 69402 (as the case requires) is payable for each test that the service comprises.

- 6. (4)** For paragraph (3) (b), the maximum number of tests to which item 66713, 66737, 66809, 66818, or 69402 applies is:

- (a) for item 66818:
2 - **X**; or
- (b) for item 66809:
3 - **X**; or
- (c) for item 66713, 66737 or 69402:
6 - **X**;

where **X** is the number of tests rendered by practitioner A in relation to the designated pathology service in respect of which the request mentioned in that paragraph is made.

6. (5) Items in Group P10 (Patient episode initiation) do not apply to the second-mentioned approved pathology practitioner in subrule (2).

Items not to be split

7. Except as stated in rule 6, the amount specified in an item is payable only to one approved pathology practitioner in respect of a single patient episode.

Creatinine ratios – Group P2 (chemical)

8. A pathology service mentioned in an item (except item 66500) in Group P2 (chemical) that:
- (a) involves the measurement of a substance in urine; and
 - (b) requires calculation of a substance/creatinine ratio;
- is taken to include the measurement of creatinine necessary for the calculation.

Thyroid function testing

9. (1) For item 66719:

abnormal level of TSH means a level of TSH that is outside the normal reference range in respect of the particular method of assay used to determine the level.

9. (2) Except where paragraph (a) of item 66719 is satisfied, the amount specified in the item is not payable in respect of a pathology service described in the item unless the pathologist who renders the service has a written statement from the medical practitioner who requested the service that satisfies subrule (3).

9. (3) The written statement from the medical practitioner must indicate:

- (a) that the tests are required for a particular purpose, being a purpose specified in paragraph (b) of item 66719; or
- (b) that the medical practitioner who requested the tests suspects the patient has pituitary dysfunction; or
- (c) that the patient is on drugs that interfere with thyroid hormone metabolism or function.

Meaning of "serial examinations or cultures"

10. For an item in Group P3 (Microbiology):

- (a) **serial examinations or cultures** means a series of examinations or cultures requested on 1 occasion whether or not:
 - (i) the materials are received on different days by the approved pathology practitioner; or
 - (ii) the examinations or cultures were requested on 1 or more request forms by the treating practitioner; and
- (b) if:
 - (i) tests are carried out in relation to a patient episode; and
 - (ii) specimen material from the patient episode is stored; and
 - (iii) in response to a request made within 14 days of the patient episode, further tests are carried out on the stored material;

the later tests and the earlier tests are taken to be part of one patient episode.

Investigation for hepatitis serology

11. (1) A medicare benefit is not payable in respect of more than one of items 69475, 69478 and 69481 in a patient episode.

11. (2) Item 69478 applies to a service in relation to which:

- (a) a practitioner requests 2 tests for immune status or viral carriage; or
- (b) the clinical notes indicate that the service is required for:
 - i. pre-operative assessment; or
 - ii. post-exposure to blood or other bodily fluids assessment; or
 - iii. assessment before blood or tissue donation.

11. (3) Item 69481 applies to a service in relation to a patient who displays one or more of the characteristics of acute or chronic hepatitis.

Tests in Group P4 (Immunology) relating to antibodies

12. For items in Group P4 (Immunology), in items 71119, 71121, 71123 and 71125, if:
- (a) tests are carried out in relation to a patient episode; and
 - (b) specimen material from the patient episode is stored; and
 - (c) in response to a request made within 14 days of the patient episode, further tests are carried out on the stored material;
- the later tests and the earlier tests are taken to be part of one patient episode.

Tests on biopsy material - Group P5 (Tissue pathology) and Group P6 (Cytology)

13. (1) For items in Group P5 (Tissue pathology):
- (a) **biopsy material** means all tissue (other than a bone marrow biopsy) received by the Approved Pathology Practitioner:
 - (i) from a medical procedure or group of medical procedures performed on a patient at the same time; or
 - (ii) after being expelled spontaneously from a patient.
 - (b) **cytology** means microscopic examination of 1 or more stained preparations of cells separated naturally or artificially from their normal environment by methods recognised as adequate to demonstrate their structure to a degree sufficient to enable an opinion to be formed about whether they are likely to be normal, abnormal but benign, or abnormal and malignant but, in accordance with customary laboratory practice, does not include examination of a blood film and a bone marrow aspirate; and
 - (c) **separately identified specimen** means an individual specimen collected, identified so that it is clearly distinguished from any other specimen, and sent for testing by or on behalf of the treating practitioner responsible for the procedure in which the specimen was taken.
13. (2) For Groups P5 and P6 of the pathology services table, services in Group P6 include any services described in Group P5 on the material submitted for a test in Group P6.
13. (3) For subrule (2), any sample submitted for cytology from which a cell block is prepared does not qualify for a Group P5 item.
13. (4) If more than 1 of the services mentioned in items 72813, 72816, 72817, 72818, 72823, 72824, 72825, 72826, 72830 and 72836 are performed in a single patient episode, a medicare benefit is payable only for the item performed that has the highest schedule fee.
13. (5) If more than 1 histopathological examinations are performed on separate specimens, of different complexity levels, from a single patient episode, a medicare benefit is payable only for the examination that has the highest schedule fee.
13. (6) In items 72813, 72816, 72817, 72818, 72823, 72824, 72825, 72826, 72830 and 72836 a reference to a **complexity level** is a reference to the level given to a specimen type mentioned in Part 5 of this Table.
13. (7) If more than 1 of the services mentioned in items 72846, 72847 and 72848 or 73059, 73060 and 73061 are performed in a single patient episode, a medicare benefit is payable only for the item performed that has the highest scheduled fee.

Items in Groups P10 (Patient episode initiation) and P11 (Specimen referred) not to apply in certain circumstances

14. (1) For this rule and items in Groups P10 (Patient episode initiation) and P11 (Specimen referred):

approved collection centre has the same meaning as in Part IIA of the Act.

institution means a place at which residential accommodation or day care is, or both residential accommodation and day care are, made available to:

- (a) disadvantaged children; or
- (b) juvenile offenders; or
- (c) aged persons; or
- (d) chronically ill psychiatric patients; or
- (e) homeless persons; or
- (f) unemployed persons; or
- (g) persons suffering from alcoholism; or

- (h) persons addicted to drugs; or
- (i) physically or mentally handicapped persons;
but does not include:
- (j) a hospital; or
- (k) a residential aged care home; or
- (l) accommodation for aged persons that is attached to a residential aged care home or situated within a residential aged care home.

prescribed laboratory means a laboratory operated by:

- (a) the Australian Government; or
- (b) an authority of the Commonwealth; or
- (c) a State or internal Territory; or
- (d) an authority of a State or internal Territory; or
- (e) an Australian tertiary education institution.

specimen collection centre has the same meaning as in Part IIA of the Act.

treating practitioner has the same meaning as in paragraph 16A(1)(a) of the Act.

14. (2) If a service described in an item in Group P10 is rendered by, or on behalf of, an approved pathology practitioner who is a recognised pathologist, the relevant one of those items does not apply to the service if:

- (a) the service is rendered upon a request made in the course of an out-patient service at a recognised hospital; or
- (b) the service is rendered upon a request made for a patient who is a private patient in a recognised hospital when the request is made; or
- (c) the pathology equipment of a recognised hospital, or a prescribed laboratory, is used rendering the service; or
- (d) a member of the staff of a recognised hospital, or a prescribed laboratory, participates in the service in the course of the member's employment with the hospital or laboratory.

14. (3) An item in Group P10 or P11 does not apply to a pathology service to which subsection 16A (7) of the Act applies.

14. (4) An item in Group P10 or P11 does not apply to a pathology service unless at least 1 item in Groups P1 to P8 also applies to the service.

14. (5) Subject to subrule (7), if one item in Group P10 applies to a patient episode, no other item in the Group applies to the patient episode.

14. (6) An item in Group P11 applies only to the approved pathology practitioner or approved pathology authority to whom the specimen mentioned in the item was referred.

14. (7) If, in respect of the same patient episode:

- (a) services referred to in 1 or more items in Group P5 and 1 or more of Groups P1, P2, P3, P4, P6, P7 and P8 are rendered by an approved pathology practitioner in the laboratory of another approved pathology authority; or
- (b) services referred to in 1 or more items in Group P6 and 1 or more of Groups P1, P2, P3, P4, P5, P7 and P8 are rendered by another approved pathology practitioner in the laboratory of another approved pathology authority;

the fee specified in the applicable item in Group P10 is payable to both approved pathology practitioners.

14. (8) If more than one specimen is collected from a person on the same day for the provision of pathology services:

- (a) in accordance with more than 1 request; and
 - (b) in or by a single approved pathology authority;
- only a single amount specified in the applicable item in Group P10 is payable for the services.

14. (9) The amount specified in item 73921 is payable only once in respect of a single patient episode.

Application of an item in Group P11 (Specimen referred) to a service excludes certain other items

15. If item 73921 applies to a patient episode, none of the items in Group P10 applies to any pathology service rendered by the approved pathology authority or approved pathology practitioner who claimed item 73921 in respect of the patient episode.

Circumstances in which an item in Group P11 (Specimen referred) does not apply

16. (1) An item in Group P11 does not apply to a referral if:
- (a) a service in respect of the same patient episode has been carried out by the referring approved pathology authority; and
 - (b) the approved pathology authority to which the referral is made is related to the referring approved pathology authority.
16. (2) An approved pathology authority is *related to* another approved pathology authority for subrule (1) if:
- (a) both approved pathology authorities are employed (including employed under contract) by the same person, whether or not the person is also an approved pathology authority; or
 - (b) either of the approved pathology authorities is employed (including employed under contract) by the other; or
 - (c) both approved pathology authorities are corporations and are related corporations within the meaning of the Corporations Act; or
 - (d) the approved pathology authorities are partners (whether or not either or both of the approved pathology authorities are individuals and whether or not other persons are in partnership with either or both of the approved pathology authorities; or
 - (e) both approved pathology authorities are operated by the Commonwealth or an authority of the Commonwealth; or
 - (f) both approved pathology authorities are operated by the same State or internal Territory or an authority of the same State or internal Territory.
16. (3) An item in Group P11 does not apply to a referral if the following common tests are referred either singly or in combination (except if the following items are referred in combination with other items not similarly specified): 65060, 65070, 65120, 66500, 66503, 66506, 66509, 66512, 66515, 66536, 66596, 69300, 69303, 69333 or 73527.

Abbreviations

17. (1) The abbreviations in Part 4 of this table may be used to identify particular pathology services or groups of pathology services.
17. (2) The names of services or drugs not listed in Part 4 of this table must be written in full.

Certain pathology services to be treated as 1 service

18. (1) In this rule:

general practitioner means a medical practitioner who:

- (a) is not a consultant physician in any specialty; and
- (b) is not a specialist in any specialty;

set of pathology services means a group of pathology services:

- (a) that consists of services that are described in at least 4 different items; and
- (b) all of which are requested in a single patient episode; and
- (c) each of which relates to a patient who is not an admitted patient of a hospital; and
- (d) none of which is referred to:
 - (i) in item 66713, 66737, 66809, 66818, 69402, 69484, 73053 or 73055; or
 - (ii) in an item in Group P10 (Patient episode initiation), Group P11 (Specimen referred) or Group P12 (Management of bulk-billed services).

18. (2) If a general practitioner requests a set of pathology services, the pathology services in the set are to be treated as individual pathology services in accordance with this rule.
18. (3) If the fee specified in 1 item that describes any of the services in the set of pathology services is higher than the fees specified in the other items that describe the services in the set:
- (a) the pathology service described in the first-mentioned item is to be treated as 1 pathology service; and

- (b) either:
 - (i) the pathology service in the set that is described in the item that specifies the second-highest fee is to be treated as 1 pathology service; or
 - (ii) if 2 or more items that describe any of those services specify the second-highest fee - the pathology service described in the item that specifies the second-highest fee, and has the lowest item number, is to be treated as 1 pathology service; and
- (c) the pathology services in the set, other than the services that are to be treated as 1 pathology service under paragraphs (a) and (b), are to be treated as 1 pathology service.

18. (4) If the fees specified in 2 or more items that describe any of the services in the set of pathology services are the same, and higher than the fees specified in the other items that describe the services in the set:

- (a) the pathology service in the set that is described in the item that specifies the highest fee, and has the lowest item number, is to be treated as 1 pathology service; and
- (b) the pathology service in the set that is described in the item that specifies the highest fee, and has the second-lowest item number, is to be treated as 1 pathology service; and
- (c) the pathology services in the set, other than the services that are to be treated as 1 pathology service under paragraphs (a) and (b), are to be treated as 1 pathology service.

18. (5) If pathology services are to be treated as one pathology service under paragraph (3) (c) or (4) (c), the fee for the one pathology service is the highest fee specified in any of the items that describe the pathology services that are to be treated as the 1 pathology service.

Hepatitis C viral RNA testing

19. For item 69444:

Hepatitis C sero-positive, for a patient, means 2 different assays of Hepatitis C antibodies are positive.

serological status is uncertain, for a patient, means any result where 2 different assays of Hepatitis C antibodies are inconclusive.

Haemochromatosis testing

20. For item 66794:

elevated serum ferritin for a patient, means a level of ferritin above the normal reference range in respect of the particular method of assay used to determine the level.

Serum B12 and red cell folate testing

21. (1) For items 66599 and 66602, a medicare benefit is not payable for more than 3 episodes of services described in item 66599 or 66602, or any combination of those items, in a 12 month period.

21. (2) A medicare benefit is not payable for a service described in item 66599 if the service was provided as part of the same patient episode as a service described in item 66602.

Nutritional and toxicity metals testing

22. (1) For this rule:

nutritional metals testing group means items 66669 and 66670.

metal toxicity testing group means items 66672 and 66673.

22. (2) An item in the nutritional metals testing group or the metal toxicity testing group does not apply in relation to a service performed if medicare benefits are paid or payable for tests that are performed for the same patient in 3 patient episodes requested within 6 months before the request for that service, under any of:

- (a) that item; or
- (b) the other item in the same group; or
- (c) an item in the other group.

Antineutrophil Cytoplasmic Antibody

23. A request for Antineutrophil Cytoplasmic Antibody immunofluorescence test (ANCA) shall be deemed to include requests for antineutrophil proteinase 3 antibody test (PR-3 ANCA) and antimyeloperoxidase antibody test (MPO

ANCA) where the immunofluorescence test for ANCA is abnormal, or has been abnormal, or those specific antibodies have been previously detected.

Satisfying Requirements Described in Items

- 24.** Unless stated elsewhere in these rules, where an item contains a requirement, this requirement is satisfied if:
- (a) The requirement/s as stipulated in the item descriptor are contained in the request form; or
 - (b) The requirement/s as stipulated in the item descriptor were supplied previously in writing to the APA and this documentation is retained by the APA; or
 - (c) The results of other laboratory tests performed in the same episode meet the requirement/s as stipulated in the item descriptor; or
 - (d) The results of laboratory tests that meet the requirement/s as stipulated in the item descriptor are supplied on the request form; or

The results of laboratory tests that meet the requirement/s as stipulated in the item descriptor are contained in the APA's records.

Limitation on certain items

- 25.**
- (a) For any particular patient, items 66539, 69442, 71075, 71127, 71135 or 71137 are applicable not more than twice in a 12 month period.
 - (b) For any particular patient, item 66626 is applicable not more than 36 times in a 12 month period.
 - (c) For any particular patient, items 66655, 66659, 69443 or 69444 are applicable not more than once in a 12 month period.
 - (d) For any particular patient, item 66750 is applicable not more than once in a pregnancy.
 - (e) For any particular patient, item 69336 is applicable not more than once in each period of 7 days.
 - (f) For any particular patient, items 69445, 71079, or 73523 are applicable not more than 4 times in a 12 month period.
 - (g) For any particular patient, item 71077 is applicable not more than 6 times in a 12 month period.

Antigen Detection – Group P3 (Microbiology)

- 26.** If the service listed in 69364 or 69365 is a pathologist determinable service the specialist pathologist is required to record the reasons for determining the need for this service.