Report of the review of Commonwealth legislation for pathology arrangements under Medicare

Final report, December 2002

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Overview

The Commonwealth provides over one billion dollars a year to support pathology services under the Medicare Benefits Schedule. Part IIA of the *Health Insurance Act 1973* is the legislative basis for the regulation of pathology services under Medicare. The objectives of this legislation are to:

- provide access to pathology services for all eligible Australian citizens;
- ensure the quality of the services that are provided; and
- prevent fraud and overservicing.

In examining the terms of reference for the Review (Appendix 1), the Steering Committee gave particular attention to:

- clarifying the objectives of the legislation; and
- identifying and setting out any alternative mechanisms that may be available to achieve the objectives of the legislation.

The Steering Committee considered whether any alternative mechanisms — regulatory or otherwise — would be able to achieve the objectives of the current legislation. The Steering Committee concluded that it was necessary to maintain the current legislative framework to achieve the objectives set out above as long as the current fee for service arrangements were retained.

The report discusses the legislative framework in detail and identifies areas that could be improved and streamlined. This regulatory framework has been complemented by two agreements between the Commonwealth Government and the pathology profession. Both agreements have sought to manage Medicare outlays on pathology services within agreed annual average rates of growth and targets. The current agreement runs from July 1999 to June 2004 and aims to save around $60 million over the life of the agreement in terms of projected expenditure. Achievement of some structural reforms and quality initiatives are other elements of the agreement.

The report describes the ways in which pathology services are funded, looks at the current fee for service arrangement and analyses the management of this fee for service arrangement. The report also describes the legislative requirements that apply to the requesting of pathology services, and considers whether the current legislative restrictions on requestors of pathology services should remain. Suggestions are provided as to ways in which the current legislative restrictions may be changed to address concerns raised in submissions to the review and to increase patient access to testing.

Much of the legislation governing the pathology arrangements under Medicare is concerned with the requirements for providers of pathology services and facilities, such as laboratories and specimen collection centres. The report analyses the current approval process for the companies that own pathology laboratories and employ pathologists, the pathologists working in the laboratories and the pathology laboratories themselves. In these areas, the Steering Committee considered that the current legislative requirements were unnecessarily cumbersome and out of step

with the current corporate environment. It identified areas of the legislation that need to be changed to make it work more effectively, to ease the regulatory burden on industry, and to address some competition issues.

In addressing the requirements for specimen collection services, the Steering Committee noted that there were a number of weaknesses with the current system. The Steering Committee considered that changes to the current legislation would not necessarily remedy these weaknesses, particularly as the current system had only recently been put in place as a solution to a number of problems that existed with the previous scheme. While the Steering Committee indicated that any future reform in this area would require large-scale changes, it noted that any further change should wait until the benefits of the newly implemented scheme had time to be realised (Recommendation 8).

The legislation also sets out specific requirements that relate to prohibited practices, enforcement and offence provisions. There are two ways in which the offence provisions may be dealt with: through the court system and via an administrative process, the Medicare Participation Review Committee. In light of the comments presented in submissions to the Review, the Steering Committee considered that there may be a more effective way to deal with penalties and suggests that further work be undertaken in this area (Recommendation 14).

The report considers new and emerging issues such as electronic ordering, point of care testing and the quality use of pathology. None of these areas are covered by the current legislation (the provision of electronic transactions is covered by the *Electronic Transactions Act 1999*) but are important in terms of the future provision of pathology services (Recommendations 16 and 17).

The report examines the changes that have taken place in the pathology industry since the introduction of the current legislation. These changes include the corporatisation of medical practices, changes in State and Territory financing arrangements, the increasing privatisation of services and changing medical practice. The impact of these changes on the current fee for service arrangement is examined.

If pathology services were to be provided in a way other than the current fee for service arrangement then Government regulation would need to be reassessed. For instance, if pathology services were to be funded through contracts with pathology providers, or through the allocation of funds to requesting practitioners, then contracts with the profession would take the place of Government regulation.

To substantiate its view that the current legislation and regulation would need to be reassessed if pathology services were funded in a different way (Recommendation 18), the Steering Committee noted some different ways in which pathology services could be funded in the future. The potential different futures for pathology funding include: different remuneration for medical and technical services; different arrangements for providing pathology collection services; development of a single funding arrangement for State and Commonwealth pathology; and budget holding.

Notwithstanding this, the Review concluded that while pathology services are provided through a fee for service arrangement, a high level of Government

regulation is required. However, the current legislative requirements need to be updated and streamlined and the following changes are recommended for immediate action:

- the approval process for pathology authorities, practitioners and laboratories needs to be streamlined and overall responsibility for services transferred to the pathology authority — or company — through a revised and strengthened undertaking (Recommendations 9 and 10);
- the requirements for pathology laboratories need to be revised so that there is a greater emphasis on quality assurance and public disclosure (Recommendation 13);
- the requirements for request forms need to be updated and streamlined (Recommendations 4 and 5);
- broadening of the membership of the Pathology Services Table Committee (Recommendation 1);
- reducing restrictions on pathologist-determinable services (Recommendation 7);
- amendment of the regulatory arrangements to provide for point of care testing (Recommendation 17); and
- making minor amendments to the legislation to align it with the current operating environment (Recommendations 12 and 15).

There were a number of areas where the Steering Committee considered further or more detailed work was required to enable conclusive recommendations to be made about regulatory change. This work is required in the following areas:

- the fee structure for pathology services and as well as the pathology rules (Recommendations 2 and 3);
- the arrangements for requestor eligibility (Recommendation 6);
- the qualification requirements for pathologists providing services under Medicare (Recommendation 11); and
- enforcement and offence provisions and processes (Recommendation 14).

Recommendations

1 The membership of the Pathology Services Table Committee should include the following representation: the Australian Association of Pathology Practices, the Royal College of Pathologists of Australasia, the Australian Medical Association, the Health Insurance Commission, the Department of Health and Ageing, public providers, requestors and health economics expertise.

2 While the current arrangements continue, the fee structure of the Pathology Services Table should be kept under review so that the allocation of resources reflects changes in technologies and pathology practice.

3 A review of each of the pathology rules of interpretation should be undertaken immediately to assess their relevance and applicability and to address the competition issues relating to the different application of the patient episode initiation fee between the public and private sectors.

4 In relation to request forms:

- the HIC should develop, promote and mandate the use of a generic request form for electronic and written requests, for use by all software companies and Approved Pathology Authorities; and
- the legislation should be amended to ensure that the following information is provided on the request form: a requestor's signature; a Medicare number; date of birth and gender of the patient; and
- that any changes in this area facilitate the use of electronic transactions.

5 The 18-month retention period that applies to the retention of request forms should be revised in line with the National Pathology Accreditation Advisory Council Guidelines for the *Retention of Laboratory Records and Diagnostic Material* that currently recommends retaining forms for three years. This timeframe for retention should be kept under constant review by the National Pathology Accreditation Advisory Council.

6 The current restrictions on the eligibility to request pathology services should be reviewed to examine the merits of extending requesting rights to nurses and/or health workers in designated remote communities where this would improve access to services.

7 So long as there is a pathology agreement which caps outlays, the restrictions on pathologist-determinable services should be reduced to grant pathologists greater discretion to request further testing necessary to make a conclusive diagnosis.

8 The current way of regulating collection centres may not be appropriate or sustainable in the longer term. However, as new arrangements for collection centres have recently been put in place, further changes in this area should be deferred until any benefits from the new arrangements have had time to be realised.

9 The Approved Pathology Authority undertaking should be strengthened and renewed on a triennial basis with frequent compliance checks. The legislation should be amended so that the Approved Pathology Authority undertakings cannot be extended for an unlimited period of time without re-approval by the Delegate.

10 The Approved Pathology Practitioner undertaking should be revised and streamlined with overall responsibility for services transferred to the Approved Pathology Authority.

11 A review of the current qualification requirements and the approval process for Approved Pathology Practitioners should be undertaken to address the following issues:

- clearer definition of a specialist pathologist, based on completion of a postgraduate program conducted by the Royal College of Pathologists of Australasia or its equivalent;
- distinction between Fellows of the Royal College of Pathologists of Australasia and other medical practitioners who perform pathology services;
- periodical assessment of the competency of persons performing pathology services and the requirement that they undertake/complete formal training in sub-disciplines in which they practise or seek to practise, and participate in appropriate continuing professional education;
- clarification of the requirements for personal supervision of services by pathologists; and
- clarification around the assessment of the qualifications of those seeking Approved Pathology Practitioner status. For instance, the appropriateness of the Health Insurance Commission using the list of qualifications developed by the National Specialist Qualification Advisory Committee needs to be examined as this committee has not been operational since 1997.

12 Subsection 23DC(17) of the Act, which relates to the provision of services by non-medical practitioners who were performing services before 1 August 1977, should be removed.

13 The following legislative changes relating to laboratory accreditation should be made immediately:

- updating the definitions of *scientist* and *senior scientist*, using those developed by the National Pathology Accreditation Advisory Council;
- removal of the definitions of *scientist* and *senior scientist* from the primary legislation (the Act) and their inclusion in delegated legislation, either in the Principles or in regulations;

- amendment of the *Health Insurance (Pathology Fees) Act 1991* to remove reference to the number of laboratory categories and include this reference in delegated legislation such as Principles or regulation;

- strengthening of the provisions that deal with underperforming laboratories;

strengthen the link between accreditation by the National Association of Testing Authorities/Royal College of Pathologists of Australasia and approval as an Accredited Pathology Laboratory;

improve the process for approving new laboratories (taking into account the new administrative changes);

ensure that laboratories are not able to operate for long periods of time when adding a new Division of testing to their current Divisions, without an inspection by the National Association of Testing Authorities/Royal College of Pathologists of Australasia;

- strengthening of the Health Insurance Commission's powers in relation to laboratories that are operating below standard;

- development of links between participation in a quality assurance program and notification of the results of this participation;

- providing for a partial refund of the approval fee for Accredited Pathology Laboratory status in appropriate circumstances; and

- extension of the renewal period for Accredited Pathology Laboratories from one to three years.

14 There is a need for further work in the area of enforcement and offence provisions and processes. This work should begin immediately and address the merits of:

- establishing a new range of offences;

- strengthening the Medicare Participation Review Committee process; and

- introducing a system of direct administrative action by the Health Insurance Commission.

15 In addition, to improve the provisions relating to enforcement, the following changes should be made to the legislation:

- insertion of the following words in 129AAA(1) '….in connection with the making of that *request or a group of requests which include that request* and, in particular, shall not make a payment …';

- insertion of the following words in 129AAA(2) 'Where an Approved Pathology Practitioner has entered into an *arrangement directly or indirectly* with a practitioner…'. It is recommended that the word *arrangement* be reviewed to establish if it is acceptable;

- strengthening of 129AAA(2) to prevent a third party service provider circumventing this provision;

- amending 129AAA(9) to include State Approved Pathology Authorities following the introduction of the new arrangements for collection centres;
- amending wording of 129AA and 129AAA to provide for consistency (within some interpretations, wording between sections has been found to be inconsistent);
- amending sections 129AAA (Bribery) and 129AAA (Prohibited practices in relation to the rendering of pathology services) as they appear to overlap and it may be possible to combine them in one section; and
- consideration of whether Clause 4 of Section 129AA can be clarified as it is not clear whether the punishment is applicable to all who are party to the prohibited practices or just the pathologist (Approved Pathology Practitioner/Approved Pathology Authority).

16 There are some areas, specific to pathology, where increased use of electronic commerce would improve the quality use of pathology. The industry is encouraged to work with the Commonwealth to embrace the following areas of development:

- the ordering and reporting of the test;
- providing feedback of the test results;
- integrating the results of the tests with tests from other pathology providers; and
- storage of results.

17 The current regulatory arrangements should be amended to provide for point of care testing where its clinical effectiveness and cost effectiveness can be demonstrated. Given the complexity of the issues surrounding the introduction of public funding for point of care testing, trials should be undertaken to determine areas where the introduction of point of care testing would be cost effective and provide increased benefits to patients.

18 If there are substantial changes to the basis on which pathology services are funded by the Commonwealth, then the nature of legislation and regulation to complement the new arrangements would need to be reassessed.

Report of the review of Commonwealth legislation for pathology arrangements under Medicare

The impetus for this Review comes from two main areas — it is part of the implementation program of the second Pathology Agreement[1] and it addresses broader Commonwealth Government reforms in the area of National Competition Policy.

The terms of reference for the Review were developed in consultation with, and were approved by, the Office of Regulation Review (ORR).[2]

The terms of reference are at Appendix 1. A Steering Committee was established to oversee the Review. The membership of the Steering Committee is given at Appendix 2.

To assist in preparing its draft report, the Steering Committee considered submissions from a broad range of stakeholders and held consultation meetings with a number of individuals and organisations. The draft report of the Review was circulated widely for public comment in July 2002. Submissions were received from a range of stakeholder groups, such as, associations and professional colleges, laboratories, Government, Divisions of General Practice, individual pathologists and other groups including the Queensland Public Sector Union and the Pathology Services Accreditation Board. A list of submissions to this second consultation phase is at Appendix 3.

A range of issues were raised in relation to the draft report, including:

- proposed changes to the membership of the peak pathology committees;
- different application of the patient episode initiation (PEI) fee to the public and private sectors;
- proposed review of the eligibility to request pathology services;
- recommendations to abolish the Approved Pathology Practitioner undertaking and transfer accountability to the Approved Pathology Authority;
- point of care testing; and
- the future directions for pathology services, including the development of a single funding pool.

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1 Since 1996–97, the Commonwealth Government has entered into two agreements with the pathology sector to manage Medicare outlays on pathology services, within agreed annual average rates of growth and targets. In addition to the Commonwealth Government, parties to the agreements are the Royal College of Pathologists of Australasia (RCPA) and the Australian Association of Pathology Practices. The agreements have included management strategies to achieve targets, both financial and non-financial.

2 The ORR has responsibility for monitoring and reporting on Commonwealth competition policy legislation reviews. The terms of reference were based on a template supplied by ORR.

The Review took into consideration comments raised in the submissions. In some cases, the Steering Committee noted comments raised in relation to particular issues, but decided not to change the recommendation. In other cases, the Steering Committee amended its recommendation, following consideration of the comments made.

Funding of pathology services

Over one billion dollars is provided annually, through the Commonwealth Medicare Benefits Scheme, for the funding of pathology services in the community and in private hospitals.

The *Health Insurance Act 1973* (the Act) establishes the Medicare Benefits Scheme and sets out the arrangements that apply to the provision of pathology services.[3] The Act also provides for a range of regulations and other pieces of delegated legislation to be made which establishes the pathology operating framework (see Appendix 4). All these pieces of legislation come under the scope of this Review.

The Act provides for the *Health Insurance (Pathology Services Table) Regulations 2001* that prescribe a table that sets out the items of pathology services, the amount of fees applicable in respect of each item and rules for interpretation.[4] This table is the Pathology Services Table (PST).

The Pathology Services Table Committee (PSTC) manages the PST. This entails drafting new, and revising existing, item descriptors and related rules of interpretation. The PSTC also advises on the interpretation of item descriptors, rules and fee setting.

Determining appropriate fee levels for pathology items — or fee setting — is a negotiated process between the PSTC and the Commonwealth Department of Health and Ageing (the Department). There is no explicit methodology for costing the services. Fees are derived from an assessment of the similarity in complexity and/or method and associated costs between the service being considered and a comparable item on the table. Implicit in this approach is that schedule fees are based on actual cost structures plus a margin for profit. In the last few years, there has been an emphasis on redressing any under-remunerated services on the table, that is, the more complex and labour-intensive services.

The PSTC works cooperatively with the Pathology Consultative Committee (PCC)[5], particularly where fee adjustments are needed to meet agreed growth targets as part of the Pathology Agreement.

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3 Health Insurance Act, Part IIA — Special provisions relating to pathology.

4 Health Insurance Act, section 4A.

5 The PCC provides a forum in which the Commonwealth and the profession can discuss strategic issues relating to the Commonwealth financing of pathology services and significant proposals for change in the arrangements under which the Commonwealth finances pathology services.

The current arrangements for managing the PST (including fee setting) recognise the specialist nature of pathology and the need for the Commonwealth Government to have expert advice from specialists in the field. However, the absence of a transparent costing structure and fee setting approach makes it difficult to assess the extent to which the process offers the Commonwealth Government the best value for money.

The following issues were raised in relation to the management of the PST:

- the perceived absence of transparency relating to the current approach to managing the PST, including the costing and fee setting process;
- the peak pathology committees and consultative arrangements (the PCC and the PSTC) may not be sufficiently representative and greater consultation with the States and Territories is required ;
- membership of the PSTC needs to be broadened;
- in some cases, the PST is not effective, is out of date and is not keeping pace with changing technology;
- rebates for services need to better reflect the costs of the services; and
- it would be beneficial to make the technical and interpretative components of tests more transparent.

Submissions to the Review agreed with the proposal to broaden the membership of the peak pathology committees[6] with many proposing that specific groups should be represented on the committees.[7] The Steering Committee considered that the PSTC would benefit from the inclusion of public providers and health economics expertise. The Steering Committee noted that representation from public pathology providers had recently been included on the PCC. The Steering Committee noted the suggestion to include consumers on the committees and decided, therefore, that both the PCC and the PSTC should be encouraged to consult more broadly and in a more structured way with consumers and consumer groups.

Recommendation 1

- The membership of the Pathology Services Table Committee should include the following representation: the Australian Association of Pathology Practices, the Royal College of Pathologists of Australasia, the Australian Medical Association, the Health Insurance Commission, the Department of Health and Ageing, public providers, requestors and health economics expertise.

Recommendation 2

- While the current arrangements continue, the fee structure of the Pathology Services Table should be kept under review so that the allocation of resources reflects changes in technologies and pathology practice.

6 Submissions: 1, 3, 4, 8, 11, 13, 18, 19, 20, 1, 24, 25, 26, 28, 29, 30, 37 and 39.

7 Submissions: 8, 18, 24, 30, 37 & 26

The Pathology Services Table — associated rules and fees

The provision of pathology services under the Medicare Benefits Schedule (MBS) is governed by a number of rules that define or clarify how services are to be interpreted and funded. These are the:

- patient episode;
- episode cone;
- patient episode initiation (PEI) fees;
- multiple services rule; and
- specimen-referred fee.

In a number of submissions, issues were raised about each of the pathology rules for interpretation, including the definition of the rule and its application. In particular:

- some sectors consider that there are differences in the way in which pathology services are provided compared with the legal definition of a patient episode. A number of submissions proposed that the definition of a patient episode be changed;
- there are perceived inequalities about eligibility for, and applicability of, the PEI fee and the episode cone between the public and private sectors which require further examination;
- in cases where specimens are referred from one laboratory to another for testing, the way in which the episode count — and subsequent benefits paid — are calculated by the Health Insurance Commission (HIC) needs to be examined to ensure it is in line with the policy;
- the exemptions to the multiple services rule are too narrow and provisions for seeking exemptions from the HIC are time consuming and not always successful; and
- the episode cone is perceived as inappropriate by some sectors of the industry.

Recommendation 3

- A review of each of the pathology rules of interpretation should be undertaken immediately to assess their relevance and applicability and to address the competition issues relating to the different application of the patient episode initiation fee between the public and private sectors.

Ordering of pathology

Request forms for pathology services

The Act does not prescribe the format of the request form for pathology services but it does provide for regulations that specify the form in which records are to be prepared, information that must be included, and how they must be kept.[8]

Request forms prepared and supplied to medical practitioners by approved pathology authorities (APAs) have to be approved by the HIC, along with any accompanying documentation.

The following issues have been raised in relation to requirements for request forms:

- the requirement for pathology request forms developed by APAs to be approved by the HIC is inconsistent, as it does not apply to third parties (such as developers of electronic ordering software);
- the approach to tick-box ordering of pathology requires review, in light of moves toward electronic ordering and the availability of decision-support software;
- some requesting practitioners do not indicate the patient's Medicare eligibility on the request form or the patient's date of birth, or gender. This requirement should be more rigorously enforced, whilst allowing for the practical difficulties in the application of some of these categories in certain situations;
- there is currently no requirement in the legislation for a practitioner to sign a request form and this should be amended;
- there is a need to eliminate separate approvals of request forms from the HIC as it is inefficient for both parties and a uniform approach to request forms should be considered;
- the issue of third parties (such as software companies) operating outside of the Medicare system for approval of request forms needs to be addressed;
- the provision of information to patients about billing practices of APAs (in particular whether a pathology practice levies a co-payment) would assist with offering patient choice in this area; and
- that any changes in this area facilitated the use of electronic signatures.

The Steering Committee noted comments made in some submissions, particularly from industry, about the lack of support for the development of a generic request form.[9] However, the Steering Committee considered that this was an important step in fostering consumer choice in relation to pathology providers.

Recommendation 4

In relation to request forms:

8 Health Insurance Act, subsection 23DKA(1).

9 Submissions 1, 6 and 39

- the HIC should develop, promote and mandate the use of a generic request form, for electronic and written requests, for use by all software companies and Approved Pathology Authorities;
- the legislation should be amended to ensure that the following information is provided on the request form: a requestor's signature; a Medicare number; date of birth and gender of the patient; and
- that any changes in this area facilitate the use of electronic transactions.

Retention of pathology request forms and other records

An Approved Pathology Practitioner (APP) is required to retain a request or a confirmation of an oral request for 18 months from the date a service is rendered in accordance with the requirements set out for requests.[10] This requirement passes to the APA if the APP leaves that practice and informs the HIC of this.

Where an APP requests another APP to perform the requested service or one of the services requested, the referring pathology practitioner has to retain the request form for a period of 18 months from the date of the original request.[11] This requirement passes to the APA where the APP ceases employment and informs the HIC of this.[12]

An APA must retain records of pathology services rendered in laboratories of which it is the proprietor.[13] The 18-month retention period allows the HIC to obtain a random sample of records over a 12-month period as well as check compliance on current claims. Where non-compliance is found, recovery of Medicare benefits is initiated.

The period of time an APP is required to keep request forms should be lengthened, to improve the HIC's auditing capacity and for conformity with the retention requirements of other Commonwealth Government agencies. Often, by the time the HIC instigates an audit, records are no longer required to be held and this hampers the HIC audit process.

The following issues have been raised in relation to requirements for request forms:

- the storage of request forms should include electronic storage and the storage of electronic transactions[14] (the NPAAC document, from which the recommendation is derived, includes both electronic storage and electronic transactions);
- any extension to the current requirements would impose a significant additional cost on pathology practices[15]; and

10 Health Insurance Act, section 16A & subsection 23DK(1).

11 Health Insurance Act, subsection 23DK(2).

12 Health Insurance Act, subsection 23DK(2A).

13 Health Insurance Act, subsection 23DKA(1).

14 Submissions: 1, 6, 13 and 29

15 Submission 23

- the NPAAC document is at odds with the some State record retention requirements.[16] The NPAAC document acknowledges the different requirements of State and Territory law and recommends minimum requirements for storage.

Recommendation 5

- The 18-month retention period that applies to the retention of request forms should be revised in line with the National Pathology Accreditation Advisory Council Guidelines for the *Retention of Laboratory Records and Diagnostic Material* that currently recommends retaining forms for three years. This timeframe for retention should be kept under constant review by the National Pathology Accreditation Advisory Council.

Eligibility – requesting, providing and collecting

For Medicare benefits to be payable for pathology services:

- the treating practitioner requesting the service must be a registered treating medical or dental practitioner, and a clinical need must be identified for that service;[17]
- if the specimen is collected at a collection centre, then the centre must be an Approved Collection Centre (ACC);
- the proprietor of the pathology laboratory must be an APA;
- the pathologist performing the test must be an APP; and
- the test must be performed in an Accredited Pathology Laboratory (APL).

This section also includes a discussion of the prohibited practices and enforcement provisions set out in the Act. Each of these provisions relates to the process of requesting and providing pathology services and collecting pathology specimens.

Requestor eligibility

As highlighted above, the treating practitioner requesting the service must be a registered treating medical or dental practitioner, and a clinical need must be identified for that service. In addition, the request or referral for a pathology service has to be in writing. Exceptions to the need for a written request apply to pathologist-determinable services. These may be performed by specialist pathologists who are also treating practitioners (eg haematologists) or by non-treating pathologists who may perform additional tests on specimens from a group of tests determined by the Minister.[18]

16 Submission 18

17 Health Insurance Act, subsections 16A(1) & 16A(12).

18 Health Insurance Act, section 4BA & subsection 16A(1).

Restrictions on requestors of pathology have had identifiable benefits for the Commonwealth Government, the pathology sector, treating practitioners, patients and the community. These include (but are not limited to):

- clarity about who is eligible to request pathology services;
- clarity and consistency in the process for requesting pathology services; and
- improved use of pathology by limiting requesting rights to those with relevant training and clinical responsibility for their patients, and to pathologists in specified circumstances.

The restrictions have also led to some difficulties, such as reduced access to services in areas where there is a shortage of medical practitioners and breaches of the Act where services are being requested by non-medical health professionals.

A number of submissions to the Review indicated that there is a need for health professionals such as nurses, midwives and health workers in Indigenous communities to be eligible to request pathology services. The submissions from nurse practitioners and midwives called for requesting rights to keep pace with the evolving role of nurse practitioners. Submissions to the second round of consultation on the draft report provided suggestions as to how any review of the restrictions on the eligibility for ordering pathology services might be approached. Comments made in the submissions to the Review will be considered as part of further work recommended in this area.

A number of members of the pathology industry consider that the range of pathologist-determinable services should be expanded. Unlike other medical specialists who may perform whatever services they deem necessary for their patients, pathologists must obtain additional requests from the treating practitioner prior to further testing being performed. The submissions argued that this requirement is paradoxical because in many instances, treating practitioners do not know the appropriate tests to order or order more tests than required.

The current requirement for the requesting practitioner to be a registered medical or dental practitioner may not always be appropriate, for example in rural and remote areas, where access to medical practitioners is limited.

The current restrictions on the professional medical services that non-clinical pathologists can order (ie pathologist-determinable services) impose a level of regulation on pathologists that does not apply to other medical practitioners.

Recommendation 6

- The current restrictions on the eligibility to request pathology services should be reviewed to examine the merits of extending requesting rights to nurses and/or health workers in designated remote communities where this would improve access to services.

Recommendation 7

- So long as there is a pathology agreement which caps outlays, the restrictions on pathologist-determinable services should be reduced to grant pathologists greater discretion to request further testing necessary to make a conclusive diagnosis.

Specimen collection

Specimens for testing are collected in a range of settings including:

- at the time of a medical consultation;
- by the patient;
- in hospital or other institution; and
- at a collection centre (previously a Licensed Collection Centre (LCC), now an ACC).

The Act specifies the circumstances under which specimens may be collected in order for Medicare benefits to be payable.[19] The specimen may be collected by the person for whom the service has been requested, the treating practitioner, or by an employee on behalf of that treating practitioner.[20] The Act also sets out different places where specimens may be collected. These include:

- the place where the person was residing;
- an ACC (previously an LCC);
- a recognised hospital;
- a private hospital, or day hospital facility, in which the person is a patient; or
- a nursing home, or other institution, in which the person is a patient.

Up until 1 December 2001, most of the legislation relating to specimen collection was concerned with the LCC Scheme. As of 1 December 2001, however, a new scheme — the ACC Scheme — replaced the LCC Scheme.

Approved Collection Centre Scheme

Under the new arrangements the number of collection centres an APA may operate is based on its MBS (including the Commonwealth Department of Veterans' Affairs) pathology episode activity over a specified 12-month period. An APA will be eligible to have one collection centre per designated number of patient episodes conducted.

The new arrangements are being phased in over four years to allow the pathology sector to adjust to a less regulated environment. Approvals are granted to APAs on a financial year basis.

Under the ACC Scheme, APAs are required to apply to the HIC annually and approval of collection centres is based on self-assessment and random audits in

19 Health Insurance Act, section 16A(5AA).

20 Health Insurance Act, paragraphs 16A(5AA)(c).

accordance with National Pathology Accreditation Advisory Council (NPAAC) collection centre guidelines.[21]

As with the LCC Scheme, the Minister allocates 'approvals' in accordance with Principles determined under the Act. The *Health Insurance (Eligible Collection Centres) Approval Principles 2001* were approved by the Minister on 24 September 2001. The Principles set out:

- general principles for applications — this includes the eligibility of premises, the way in which an application for approval may be made and the timing of applications;[22]
- a system for determining the maximum number of approvals that may be granted to a particular APA in respect of a financial year;[23] and
- other matters, including the effect of acquisition or disposal of APA businesses, the effect of merger of APA businesses and review of decisions.[24]

One of the major eligibility changes implemented as part of the new arrangements is the requirements that the APA applying for approval must be the sole proprietor of a Category G laboratory.

However, there have been two amendments to this requirement. The first amendment was made on 8 October 2001 and allowed for laboratories that were not Category G laboratories but were in rural and remote areas and were associated with a Category G laboratory to participate in the ACC Scheme.

On 26 November 2001, a further amendment was made that allowed Category S laboratories that were participating in the LCC Scheme prior to 1 December 2001 and that were operating LCCs to retain their collection centres.

The following issues were raised in regard to arrangements for collection centres:

- restrictions around the entry and participation in the ACC arrangements are contentious;
- the lack of public sector access to PEI fees will continue to be an issue under the arrangements that were introduced on 1 December 2001;
- collection centres are a high growth area and are currently the major avenue for specimen collection;
- the role of collection centres in attracting business coupled with the limitation on their numbers gives them commercial value greatly exceeding the value of the physical assets involved;
- there are concerns that collection centres are used by larger pathology companies to constrain competition and that smaller players are placed at a disadvantage;

21 NPAAC (2000) *Guidelines for Approved Pathology Collection Centres.* Commonwealth Department of Health and Aged Care, Canberra.

22 Health Insurance (Eligible Collection Centres) Approval Principles 2001, Part 2.

23 Health Insurance (Eligible Collection Centres) Approval Principles 2001, Part 3.

24 Health Insurance (Eligible Collection Centres) Approval Principles 2001, Part 4.

- laboratories and clinical practices are increasingly under common corporate ownership, with the laboratory guaranteed referrals by the tied collection centre;
- there are very few collection centres in rural and remote locations, reducing access to pathology services for patients in these areas;
- the current arrangements do not place sufficient emphasis on uniformity in the quality of services and facilities at the centres, and are cumbersome to administer by all parties;
- it is questionable whether the use of collection centres is the most cost effective way of collecting and transporting pathology specimens;
- the regulation of collection centres creates a substantial barrier to entry for new pathology providers or to existing providers extending their service to new geographic regions; and
- some stated that an immediate review of the current arrangements is required,[25] while others stated that any further review should not take place until the benefits of the new ACC scheme have been realised[26], others considered that a further review of the ACC arrangements was not required at all [27].

These issues are broadranging and suggest broader policy based consideration is required.

25 Submissions 8 and 35

26 Submissions: 1, 3, 4, 18, 29 and 39

27 Submission number 6

Recommendation 8

- The current way of regulating collection centres may not be appropriate or sustainable in the longer term. However, as new arrangements for collection centres have recently been put in place, further changes in this area should be deferred until any benefits from the new arrangements have had time to be realised.

Eligibility requirements for Approved Pathology Authorities

To be eligible to provide pathology services under Medicare, the Act requires that the proprietor of the laboratory in which the pathology services are being performed must be an APA.

Unlike the eligibility requirements for APPs, there are no specific qualifications required for an entity to become an APA.

To receive APA status, the applicant must sign an undertaking in the approved form and apply to the Minister for acceptance of the undertaking. The Minister may accept or refuse to accept the undertaking.[28] The application for acceptance must include particulars as determined by the Minister by disallowable instrument.[29] The Minister determines the period of effect of the undertaking up to a maximum of 12 months. A person is an APA during the period the undertaking is in force. In practice, this means that approvals are renewable annually.[30]

The particulars determined for an application by a company can include particulars of the directors, shareholders and officers of the company.[31]

In common with the APP application form, the APA form also requests information on any offences, notices, recommendations or orders relevant to the Act or the *Crimes Act 1914* or any determinations by the Medicare Participation Review Committee (MPRC).

As with the APP undertaking, the APA undertaking is a declaration made by the applicant to abide by a set of practices.[32] Several sections of the APA undertaking are mirrored in the APP undertaking.[33]

28 Health Insurance Act, subsection 23DF.

29 Health Insurance Act, subsections 23DF(13) to (15).

30 Health Insurance Act, subsections 23DF(1) & (2).

31 Health Insurance Act, subsection 23DF(3).

32 Documents for applicants applying for acceptance of an approved pathology authority (APA) undertaking. Health Insurance Commission, http://www.hic.gov.au.

33 The Minister for Health and Ageing approved changes to both the APA and APP undertakings in November 2002. The new undertakings will take effect from 1 January 2003.

The following issues were raised about the APA undertaking:

- the changing structure of the pathology industry has led to an overall decrease in the total number of APAs and an increase in the proportion of APAs that are company owned;
- developments in the pathology industry have led to changing roles and responsibilities for APPs and APAs;
- duplication is present in the application requirements for APPs and APAs;
- a large proportion of APAs are operating on extended undertakings; and
- evidence suggests that the APA undertaking in its current form is not achieving its original purpose.

Recommendation 9

- The Approved Pathology Authority undertaking should be strengthened and renewed on a triennial basis with frequent compliance checks. The legislation should be amended so that the Approved Pathology Authority undertakings cannot be extended for an unlimited period of time without re-approval by the Delegate.

Eligibility requirements for Approved Pathology Practitioners

For Medicare benefits to be paid for the services they perform, pathology practitioners must be granted APP status.[34] APPs must be medical practitioners but need not be pathologists.[35] Other specialists (such as obstetricians, gynaecologists and fertility specialists) and general practitioners can be approved as APPs. An exception to this definition applies to persons who before 1 August 1977 were performing pathology services at the request of medical practitioners and receiving benefits for this work.[36] The HIC advises, however that all current APPs are medical practitioners and this provision is no longer needed.

To be accepted as an APP, the practitioner must complete an application for acceptance of an APP undertaking. The applicant must provide general details about him or herself, including current medical practitioner registration details, registered professional qualifications and financial interests.

The undertaking is a declaration made by the applicant to abide by a set of practices.[37] These relate to: personal supervision; agreements and arrangements with interested parties; multiple pathology services; excessive pathology services;

34 This requirement does not apply to medical practitioners performing tests listed in Group P9 of the MBS where these are performed in the context of a medical consultation or for patients of other doctors in the same group practice.

35 Health Insurance Act, section 23DC.

36 Health Insurance Act, subsection 23DC(17).

37 Documents for applicants applying for acceptance of an approved pathology authority (APA) undertaking. Health Insurance Commission, http://www.hic.gov.au, pp 3–4.

accounts, receipts and assignment of Medicare benefit; advertising; supply of information; offences; persons acting on their behalf; and notices.

The following issues were raised about the APP application process and undertaking:

- the APP undertaking has not been revised since its introduction in 1986 and it is in need of updating;
- some considered that it may be appropriate to abolish the APP undertaking and reinforce the APA undertaking to reflect the changes in pathology practice and industry structures. However, others considered that the APP undertaking should be retained to ensure and maintain the quality of pathology services; [38]
- the definitions of *specialist pathologist*, *scientist* and *senior scientist* require revision;
- it may be appropriate to introduce a fee structure for the services of specialists who provide professional input as distinct from fees for the non-medical, technical aspects of testing;
- the part of the legislation that provides that only specialist pathologist APPs are eligible to claim PEI fees needs to be clarified;
- the current qualifications for becoming an APP require revision, along with the mechanism for approving these qualifications;
- consideration should be given to periodically assessing the competency of persons performing pathology services and introducing a requirement for formal training in each of the sub-disciplines in which they practise or seek to practise. Participation in continuing professional education could also be a requirement. This move would be consistent with the national approach in this area, where there are initiatives aimed at assessing the standards of continuing professional development and discussions about linking medical registration to some evidence of on-going competency;
- differing views on requirements for personal supervision of services by pathologists have been raised, with some seeking to strengthen this role and others arguing that volume and automation of the majority of services make this requirement irrelevant;
- the legislation and APP undertaking still make reference to the term *excessive pathology services*, which was replaced by the term *inappropriate practice* in 1994;
- the legislation currently allows undertakings to be extended indefinitely; and
- consideration should be given to the removal of subsection 23DDA(1)(a) to remedy the situation whereby backdating of the undertaking is restricted if a decision is not made within one month.

38 Submission 1, 6, 18, 23, 28 and 39

The APP undertaking

The Review considers that the APP undertaking is not a particularly effective instrument in ensuring compliance. This is attributable to significant changes in the structure and ownership of pathology practices, how they are run, the way the majority of pathology services are performed and the role of the pathologist. However, the pathology practitioner continues to be held accountable for actions largely outside their sphere of influence, a point emphasised in many submissions to the Review. Another point emphasised in submissions to the Review was the important role that the pathologist plays in ensuring the quality of pathology services. Most of the requirements contained in the APP undertaking are also in the APA undertaking.

Recommendation 10

- The Approved Pathology Practitioner undertaking should be revised and streamlined with overall responsibility for services transferred to the Approved Pathology Authority.

Re-examination of the qualifications required to become an APP

Discussion has highlighted complexities relating to the qualifications that are required to become an APP as well as with the approval process. These relate to differentiating between medical practitioners who have completed a formal postgraduate course of study and training in sub-disciplines of pathology and those who have not. These sentiments were reiterated in the second round of consultation[39], and some went even further, suggesting that scientists should not be excluded from practicing as APPs.[40]

39 Submissions 6 and 10

40 Submissions 8 and 18

Recommendation 11

- A review of the current qualification requirements and the approval process for Approved Pathology Practitioners should be undertaken to address the following issues:

- clearer definition of a specialist pathologist, based on completion of a postgraduate program conducted by the Royal College of Pathologists of Australasia or its equivalent;
- distinction between Fellows of the Royal College of Pathologists of Australasia and other medical practitioners who perform pathology services;
- periodical assessment of the competency of persons performing pathology services and the requirement that they undertake/complete formal training in sub-disciplines in which they practise or seek to practise, and participate in appropriate continuing professional education;
- clarification of the requirements for personal supervision of services by pathologists; and
- clarification around the assessment of the qualifications of those seeking Approved Pathology Practitioner status. For instance, the appropriateness of the Health Insurance Commission using the list of qualifications developed by the National Specialist Qualification Advisory Committee needs to be examined as this committee has not been operational since 1997.

Recommendation 12

- Subsection 23DC(17) of the Act, which relates to the provision of services by non-medical practitioners who were performing services before 1 August 1977, should be removed.

Eligibility requirements for Accredited Pathology Laboratories

Another eligibility criterion for the payment of Medicare benefits for pathology tests is that the laboratory in which the tests are performed is an APL.

The approval process that applies to APLs varies considerably from the APP and APA approval processes.

To be eligible for approval as an APL an applicant must:

- submit an application for approval of premises as an APL for consideration by the Minister;
- have the laboratory assessed by the National Association of Testing Authorities/Royal College of Pathologists of Australasia (NATA/RCPA); and
- pay an application fee following approval in principle by the Minister.

The Act and the *Health Insurance (Accredited Pathology Laboratories — Approval) Principles 1999* (the Principles) provide the legislative basis for the accreditation of laboratories by an independent body (currently NATA/RCPA) as well as the approval process by the HIC.

The Principles set out the categories for pathology laboratory accreditation, stipulate supervisory requirements and make reference to a number of accreditation materials, developed by NPAAC that are used as part of the accreditation process. The Principles also provide for the Minister to consider matters such as whether the laboratory:

- is accredited to perform tests in particular groups of pathology;
- requires staff to participate in relevant continuing education programs;
- participates in appropriate quality assurance programs; and
- is adequately equipped to carry out the pathology services provided.

These eligibility requirements provide a basis for ensuring that the Commonwealth Government is paying Medicare benefits for cost effective, high quality pathology services.

The application form for approval of premises as an APL requires the applicant to provide information, such as: laboratory details; details of the proprietor; details of the person having direction, control and supervision in the laboratory; staffing and staff qualifications; and the services carried out by the laboratory.

The following issues were raised in relation to pathology laboratory accreditation and APLs:

- supervision of Category GX and GY laboratories — this issue has been contentious since the introduction of a new category structure by NPAAC in January 2000;
- the Act should not stipulate the number of laboratory categories;
- there are currently weaknesses in the provisions to deal with underperforming laboratories and public notification and this needs to be strengthened;
- the link between NATA/RCPA accreditation and HIC approval as an APL needs to be strengthened in the legislation, as does the process for approving new laboratories and the process of adding a new Division of testing to the APL approval;
- the links between participation in a quality assurance program and notification of the results of this participation need to be strengthened;
- a review of the fee structure for laboratory accreditation is required;
- partial refund of the approval fee should be considered in appropriate circumstances; and
- consideration should be given to extending the renewal period for APLs from one to three years.

Recommendation 13

The following legislative changes relating to laboratory accreditation should be made immediately:

- updating the definitions of *scientist* and *senior scientist*, using those developed by the National Pathology Accreditation Advisory Council;
- removal of the definitions of *scientist* and *senior scientist* from the primary legislation (the Act) and their inclusion in delegated legislation, either in the Principles or in regulation;
- amendment of the *Health Insurance (Pathology Fees) Act 1991* to remove reference to the number of laboratory categories and include this reference in delegated legislation such as Principles or regulations;
- strengthening of the provisions that deal with underperforming laboratories;
- amendment of the Principles to:

- strengthen the link between accreditation by the National Association of Testing Authorities/Royal College of Pathologists of Australasia and approval as an Accredited Pathology Laboratory;
- improve the process for approving new laboratories (taking into account the new administrative changes); and
- ensure that laboratories are not able to operate for long periods of time when adding a new Division of testing to their current Divisions, without an inspection by the National Association of Testing Authorities/Royal College of Pathologists of Australasia.

- strengthening of the Health Insurance Commission's powers in relation to laboratories that are operating below standard;
- development of links between participation in a quality assurance program and notification of the results of this participation;
- providing for a partial refund of the approval fee for Accredited Pathology Laboratory status in appropriate circumstances; and
- extension of the renewal period for Accredited Pathology Laboratories from one to three years.

Prohibited practices, enforcement and offence provisions

The Act sets out a range of prohibited practices that apply at different points in the process of providing pathology services.

The offence provisions in the legislation differ in scale and severity depending on the practice that is being regulated. There are two ways in which the offence provisions in the pathology legislation may be dealt with — through the court system (through the enforcement of penalties) and via an administrative process (the MPRC).

All the penalties enforced through the court system are linked to a criminal sanction and the penalties may include a monetary fine,[41] imprisonment[42] or both.[43] The MPRC may make determinations, such as to counsel or to issue a reprimand or require that Medicare benefits be repaid. The MPRC may also determine that no undertaking is to be accepted for a specified period or that no Medicare benefits are payable for a specified period.[44] There is a right of review of determinations by the MPRC to the Administrative Appeals Tribunal.[45]

For ease of analysis, the offence provisions have been grouped as follows:

- general offence provisions;
- serious offence provisions; and
- provisions relating to APA and APP undertakings and the MPRC process.

General offence provisions

The general offence provisions cover:

- offences in relation to disqualification of a practitioner (section 19DB);
- records to be kept by APAs (section 23DKA);
- revocation of approvals for specimen collection centres (section 23DNG);
- inspection of specimen collection centres (section 23DNJ);
- people to be told if a specimen collection centre is unlicensed (section 23DNL);
- display of notice that a specimen collection centre is licensed (section 23DNK); and
- not keeping or producing pathology requests or confirmations (section 23DP).

Serious offence provisions

Part VII of the Act sets out various provisions relating to serious offences such as:

- making false or misleading statements capable of being used in connection with a claim for Medicare benefits (section 128A);
- bribery (section 129AA); and
- inducements (section 129AAA).

Provisions relating to APA and APP undertakings and the MPRC process

As mentioned above, APPs and APAs are required to make undertakings which must be accepted by the Minister in order for them to be eligible for Medicare benefits for services they perform.

Section 124E of the Act provides for the Chairperson to establish an MPRC on receiving certain notices. These include notices under section 124D on conviction

41 Health Insurance Act, sections 19D(2), 23 DKA(1), (2), (3) & 23DNL.

42 Health Insurance Act, section 129AAA(8).

43 Health Insurance Act, section 128B.

44 Health Insurance Act, section 124F.

45 Health Insurance Act, section 124R.

of a practitioner of a relevant offence. A relevant offence is defined in section 124B to cover various offences in sections 128A, 128B, 129, 129AA and 129AAA dealing with false statements, bribery and relevant provisions of the *Crimes Act 1914*.

Sections 124FB and 124FC set out the determination which an MPRC can make where it determines that an APP or an APA has breached its undertaking. If the breach consists of rendering excessive pathology services, the MPRC must identify the services.[46] The possible determinations an MPRC can make if it determines that an APP has breached an undertaking are:[47]

- no action, counselling, reprimand or revocation of the undertaking;
- no undertaking to be accepted for a specified period of up to five years;
- no Medicare benefits payable for a specified kind of pathology service for a specified period of up to five years;
- Medicare benefit (or part) to cease to be payable to the practitioner if unpaid; and
- that Medicare benefits paid or payable to someone else be payable by the APP to the Commonwealth Government.

The possible determinations a MPRC can make if it determines that an APA has breached the undertaking are:[48]

- no action, counselling, reprimand of the APA, its employee, or an officer of the company;
- revocation of the undertaking;
- no undertaking to be accepted for a specified period of up to five years; and
- that Medicare benefit paid or payable to a person other than the APA be payable by the APA to the Commonwealth Government.

However, the outcome of the MPRC process — most of the determinations made are of a minor nature — demonstrates that the MPRC needs to be strengthened if it is to be relied on as the major avenue through which breaches of the legislation are to be pursued.

There are a range of issues relating to the effectiveness of the prohibited practices and enforcement measures currently set out in Act, including that:

- the undertaking is a potentially strong enforcement measure, particularly as it can be revoked through the MPRC process. However, it appears that the MPRC process could be improved and that a range or scale of determinations may make the process more effective;
- some of the offence provisions are not effective due to changes in the operating environment, such as the new business structures in pathology and general

46 Health Insurance Act, paragraph 124FB(1)(d) for an APP & 124FC(1)(d) for an APA

47 Health Insurance Act, paragraph 124FB(1)(e).

48 Health Insurance Act, paragraph 124FC(1)(e).

practice and the introduction of electronic ordering, and changes to these areas may be required;

- further exploration of the merits of changing some of the offence provisions from criminal to civil, or developing a new set of provisions, is required. The deficiencies of using criminal law in this area were also raised again as part of the second round of consultation[49];
- the role of the HIC in enforcing the legislation could be strengthened; and
- changes to enforcement and offence provisions need to ensure that prohibited practices can be dealt with effectively[50].

Many aspects of the current scheme should, in theory, be working effectively to stop fraud and other illegal practices. The legislation also provides for both legislative and administrative redress of any breaches of the legislation. The major problem appears to revolve around the high standard of proof that is required in the court system and the difficulties thus posed in securing the Director of Public Prosecutions' agreement to pursue cases. Other problems appear to be the changing nature of pathology business structures and the inability of the legislation to keep pace with these changes. Additionally, the MPRC process that should operate as an effective alternative to the court system, has been used infrequently over the years since its introduction and it seems that the range of determinations it can make are too limited.

The relevant questions are whether there is scope to change aspects of the current legislation to solve these problems and whether removing the provisions from the criminal code and placing them in the civil or administrative code would necessarily improve the system.

In addition, submissions to the review offered suggestions as to ways in which the current legislation in this area could be improved. These comments are detailed in the background material.

Recommendation 14

There is a need for further work in the area of enforcement and offence provisions and processes. This work should begin immediately and address the merits of:

- establishing a new range of offences;
- strengthening the Medicare Participation Review Committee process; and
- introducing a system of direct administrative action by the Health Insurance Commission.

49 Submission 23

50 Submission 25

Recommendation 15

In addition, to improve the provisions relating to enforcement, the following changes should be made to the legislation:

- insertion of the following words in 129AAA(1) '….in connection with the making of that *request or a group of requests which include that request* and, in particular, shall not make a payment …';
- insertion of the following words in 129AAA(2) 'Where an Approved Pathology Practitioner has entered into an *arrangement directly or indirectly* with a practitioner…' It is recommended that the word *arrangement* be reviewed to establish if it is acceptable;
- strengthening of 129AAA(2) to prevent a third party service provider circumventing this provision;
- amending 129AAA(9) to include State Approved Pathology Authorities following the introduction of the new arrangements for collection centres;
- amending wording of 129AA and 129AAA to provide for consistency (within some interpretations, wording between sections has been found to be inconsistent);
- amending sections 129AAA (Bribery) and 129AAA (Prohibited practices in relation to the rendering of pathology services) as they appear to overlap and it may be possible to combine them in one section; and
- consideration of whether Clause 4 of Section 129AA can be clarified as it is not clear whether the punishment is applicable to all who are party to the prohibited practices or just the pathologist (Approved Pathology Practitioner/Approved Pathology Authority).

Issues for the future

Electronic commerce

Developments in information technology, such as electronic requesting and ordering, have added a new dimension to the way in which pathology services may be provided. As developments in electronic ordering, requesting, storage, and transmission of results continue to occur, the future provision of pathology services will be dramatically altered and improved as they become integrated with other areas of medicine.

As of 1 July 2001, the *Electronic Transactions Act 1999* accorded electronic transmissions the same status as written documents, with Commonwealth agencies retaining the right to prescribe the format of electronic messages (eg software, mailbox, and digital signatures) where transactions are subject to Commonwealth legislation.

The HIC has assisted the use of electronic commerce through the development of information technology standards for use under the *Electronic Transactions Act 1999*. These standards are to be used for the electronic transmission of all requests for, and confirmation of requests for, pathology services to APPs.

There are a number of uses of electronic transactions or electronic commerce in the provision of pathology services. These include:

- use of electronic request forms;
- submission of electronic requests;
- electronic storage of pathology request forms;
- electronic integration of results from different pathology providers; and
- expansion of electronic payment options.

A number of submissions to the Review discussed issues relating to electronic commerce in pathology and expressed an interest in the use of electronic request forms. Many of the submissions made recommendations or suggestions about the areas, relating to electronic commerce, that the Commonwealth Government should address. These suggestions may be grouped into three main areas:

- recognition of electronic request forms (including electronic signatures) without the need for a paper follow up;
- changing the audit practices from a paper-based audit to an audit of the electronic record;
- expansion of electronic payment options;
- the need to recognise electronic results reporting as an approved alternative to paper reports; and
- that there is a need for standardised test codes to be adopted and that there may need to review the definition of 'result; in the *Electronic Transactions Act 1999*.

Developments in electronic commerce may also have a number of potential benefits, including:

- increasing administrative efficiency and thereby reducing administrative costs (one submission commented that the HIC systems need to be improved so that electronic transactions can be used for pathology requesting, reporting and billing purposes[51]);
- increasing the range of information available for clinical decision-making and rational test ordering and in doing so improving health outcomes;
- that safeguards need to be in place to protect the rights of individuals;[52]
- greater efficiencies if integrated with other area of medicine;[53]

51 Submission 18

52 Submission 40

53 Submission 1

- improving access to data and thereby increase knowledge of the industry; and
- enabling more comprehensive audit procedures to be undertaken which may in turn generate cost savings through greater compliance with the Act.

Recommendation 16

There are some areas, specific to pathology, where increased use of electronic commerce would improve the quality use of pathology. The industry is encouraged to work with the Commonwealth to embrace the following areas of development:

- the ordering and reporting of the test;
- providing feedback of the test results;
- integrating the results of the tests with tests from other pathology providers; and
- storage of results.

Point of care testing

Point of care testing (PoCT) — also known as near patient testing (NPT) — is a 'pathology investigation by or on behalf of the treating medical practitioner on-site, at the time of and for use during consultation'.[54] PoCT means that a pathology sample does not have to be referred to a laboratory — the medical practitioner or health care worker undertakes the test during the consultation — and the result of the test may be known immediately or within minutes of the test being undertaken.

Over the last few years, there have been major technological advances in the area of PoCT and a number of tests are now available. However, the PST does not provide Medicare rebates for PoCT apart from those that can be performed under Group P9 of the PST. Tests in Group P9 of the MBS are defined as 'simple and basic' pathology tests that do not require a formal quality assurance process. To be eligible to receive Medicare benefits for more complex tests, general practitioners must become an APA and an APP and become accredited as an APL. To become accredited as an APL, inspection of the practitioners' premises by NATA/RCPA is required, as is participation by the practitioner in a quality assurance program for the tests they perform. The costs involved in becoming an APA, an APP and an APL are high (estimated at over $4,000 per annum)[55] and many general practitioners claim that they would like to undertake PoCT but cannot afford the high costs involved.[56]

The Commonwealth Government is coming under increasing pressure to introduce Medicare rebates for PoCT. At the same time it is being asked to change the regulatory requirements so that PoCT can be performed by general

54 Commonwealth Department of Health and Aged Care (2001) *Review of the Role and Value of Near Patient Testing in General Practice.* Unpublished report prepared for the Department, Canberra, p.7

55 Commonwealth Department of Health and Aged Care (2001) *Review of the Role and Value of Near Patient Testing in General Practice.* Unpublished report prepared for the Department, Canberra, p.84

56 Commonwealth Department of Health and Aged Care (2001) *Review of the Role and Value of Near Patient Testing in General Practice.* Unpublished report prepared for the Department, Canberra, p.85 and Submissions 12 & 13.

practitioners and/or other health care workers without the full range of eligibility criteria, required of larger pathology laboratories, applying to these services.

PoCT has a range of potential benefits, such as:

- convenience and satisfaction for patients — through quicker diagnosis and treatment decisions with fewer visits to the doctor;
- enhanced clinical management — better monitoring of certain chronic conditions, improved therapeutic control, more rational prescribing, improvement of the doctor-patient relationship, better clinical decisions within the consultation timeframe;
- greater patient compliance with pathology requests;
- better health outcomes for the patient;
- greater satisfaction for the general practitioner; and
- savings in cost and time.

However, like any health technology, PoCT can also have disadvantages, including:[57]

- inappropriate testing (or screening) leading to increased costs with no benefits to the patient;
- inaccurate results which lead to less than optimal health outcomes for the patient with additional (sometimes invasive) testing and treatment; and
- increased consultation time and cost.

The submissions to the Review that addressed the issue of PoCT supported the new technology.

PoCT offers patients a range of potential benefits and may also provide a number of cost savings to the Commonwealth, particularly in rural and remote areas. As the PoCT technology is still evolving, it is important that any regulatory framework established by the Commonwealth Government to provide for PoCT is flexible and can be amended and updated as required.

The Review considered there were three possible options for introducing PoCT. Firstly, the Steering Committee looked at whether PoCT could be introduced as part of Group P9 of the PST. However, as much PoCT is more complex than the simple basic pathology tests, the Steering Committee considers, that this would not be appropriate.

The Steering Committee then considered whether PoCT could be introduced through a 3C determination. Section 3C of the Act provides for the Minister to determine that a specified health service not described in the MBS shall, in specified circumstances, be treated as if it were an item in the MBS. It may be appropriate for specific tests used in PoCT to be placed on the MBS as part of a 3C determination where data collection is required and/or where the test is being

57 Commonwealth Department of Health and Aged Care (2001) *Review of the Role and Value of Near Patient Testing in General Practice.* Unpublished report prepared for the Department, Canberra, p.14

introduced into a specific population group that requires monitoring of its effectiveness.

However, there are legislative impediments for using Section 3C determinations for the ongoing funding of tests and, as such, the use of Section 3C determinations could not be seen as a permanent solution to the issue of PoCT.

In light of the issues discussed above, it was considered that a different set of arrangements for medical practitioners to undertake PoCT might be required. Any new arrangements must address the following issues:

- who can order PoCT;
- how the quality assurance would work;
- what tests could be undertaken;
- how the audit trail would work;
- availability of test results; and
- clinical restrictors.

The following issues were raised in relation to PoCT:

- that PoCT should have the same quality control standards applied as currently apply to laboratory testing and that the testing should be done under the supervision of a pathologist[58];
- comments from GPs undertaking PoCT focussed on the current requirement for them to become an APA, an APP and an accredited Category M labortory. These submissions advocated reducing the fees for Category M laboratories[59];
- that selected pilot testing for PoCT is not necessary and that a national roll out should take place;[60]
- other submissions advocated the case for PoCT to be undertaken in community pharmacies[61]; and
- broadening of the definition of PoCT to include screening.[62]

Recommendation 17

- The current regulatory arrangements should be amended to provide for point of care testing where its clinical effectiveness and cost effectiveness can be demonstrated. Given the complexity of the issues surrounding the introduction of public funding for point of care testing, trials should be undertaken to determine areas where the introduction of point of care testing would be cost effective and provide increased benefits to patients.

58 Submissions 4, 18, 19, 25 and 35.

59 Submissions 5 and 11

60 Submission 39

61 Submissions 21 and 30

62 Submission 30

Different futures for pathology arrangements?

Since the introduction of the current form of the pathology legislation, a number of significant changes have taken place in the pathology industry. These include the corporatisation of medical practices, changes to State and Territory financing arrangements, and increasing levels of privatisation of services.

These changes mean that existing arrangements may not always be appropriate. It is likely that at the end of the current Pathology Agreement, both the industry and Government will be looking for some revision to the broad framework of arrangements.

The Steering Committee considered that its findings with respect to the legislation and regulation hold true for the current framework of arrangements for pathology. However, were the framework to be adjusted the role of legislation and regulation may well also change. For example, a number of elements of the current legislation and regulation are concerned with the boundary between Commonwealth and State financial responsibilities. If at any time in the future, this boundary were to change or be removed, then the role of legislation and regulation would also have to change.

The changing environment

Corporatisation of pathology practices

The trend towards corporatisation in the pathology industry (and in the medical industry more broadly) has dramatically changed the way in which diagnostic services such as pathology are provided. Over the past few years, corporate owners of APAs have been particularly active in acquiring APAs and acquisition and consolidation in the industry has resulted in a significant increase in concentration at the ownership level.

This trend has a range of implications for the industry, the Commonwealth, and National Competition Policy, namely that:

- concentration is increasing within the pathology industry and many of the company APAs are owned by the same parent company;
- the relationship between the pathology industry and Government has changed as Government is now dealing with big corporate entities; and
- concentration has allowed the main companies to gain productivity improvement through economies of scale and more efficient processes.

A potential risk to the Commonwealth is that if these trends continue, pathology companies may look at other ways in which to increase their revenue and profits and the quality of the testing may decline, and/or out-of-pocket costs to patients will increase. At the moment, the rate of bulk billing for pathology services is high — between 1984–85 and 1999–2000 the level of bulk billing for pathology services increased by 38.6 per cent while schedule fee observance decreased by

3.1 per cent in the same period. This is significantly higher than the 27.1 per cent growth in bulk billing observed for all services across the same period.[63]

The corporatisation of medical practices has had a number of effects. It means that the pathology industry has become dominated by larger and more profit-focussed companies with large and effective marketing capacities. The industry has become vertically integrated and that has led to pressure to increase demand.

Changes in State and Territory policies on the provision of public pathology

A number of significant changes occurred in the late 1980s and 1990s in Commonwealth and State Government policies in response to the adoption of market-based approaches to public sector activities. Governments overall looked at opportunities to gain efficiencies in their jurisdictions by market testing. This led to tendering and contracting of public utilities and privatisation of others. In the public hospital sector, this included diagnostic, outpatient and emergency services, hotel and other ancillary services.

This period also saw significant changes in the way in which acute health care is delivered, with a greater emphasis on out-of-hospital care. This meant that patients admitted to hospitals were more likely to be sicker than before. This period also saw the shift to community-based care for aged people and those with chronic illnesses through joint Commonwealth and State and Territory Government initiatives such as day surgery, home and community care program and coordinated care trials. The effect of these changes on costs to the different levels of Government can only be approximated. However, there are some assumptions that can be made about the effect of these policies and programs. These include more pre-admission diagnostic work being done in the community setting and early discharge into the community, with the local doctor providing more care. For pathology, this meant that services previously provided to patients at no cost in the hospital system were billed against Medicare.

Arrangements such as these mean that private pathology practice gains access to the public pathology services as well as the pathology generated by privatised outpatient work and is able to charge a PEI fee for this private work.[64]

Change in status of the charitable sector

Traditionally, the charitable sector has been regarded as an extension of the public sector, as it is funded by various sources, including State Government grants. It also receives some favourable taxation arrangements not available to the private sector.

In October 2001 there were 11 charitable sector pathology providers. For the purposes of pathology arrangements, these organisations are regarded as private sector operators. This status makes them eligible to charge patients the PEI and

63 Commonwealth Department of Health and Aged Care (2001). *Medicare Statistics 1984-85 to December Quarter 2000.* Canberra. p.11.

64 *Submission 33,* page 6 provides an example of the implications of such an arrangement for private and public pathology providers

specimen-referred fees and it also allowed them to participate in the LCC arrangements. This has led to considerable acrimony within the industry, as the charitable sector is perceived to have an unfair advantage over both the public and private sectors, by maximising their financial advantages. Under the previous LCC arrangements, the public sector was excluded from the LCC arrangements. From 1 December 2001 the public sector was able to participate in new collection centre arrangements, however it is still unable to claim PEI or specimen-referred fees.

The impact of increasing corporatisation of the charitable sector has been a modest increase in expenditure in these fees. It is recognised that this sector has financial advantages when compared with the private and public sectors.

The changing nature of medical practice

Medicare data show that there is an upward trend in the number of services requested per patient episode by general practitioners and specialists. This is despite low growth in consultations for these groups over the past few years. Benefits paid per episode are growing at a faster rate than the services requested per episode. This is the result of more expensive services being requested.

There are various views about what is driving the high growth in pathology requests and the shift towards more expensive services. Possible reasons include changes in health care delivery practices by medical practitioners, the changing profile of medical practitioners and their ordering patterns,[65] and increases in supply and demand for pathology services. Other influences relate to structural developments, such as increased marketing of services by pathology practices to requesting practitioners, and ownership of medical practices by pathology practices. There are also increased consumer expectations, more knowledgeable consumers, fear of litigation by medical practitioners, and greater availability of tests. Other factors are a lack of information among medical practitioners about the costs of tests ordered and the high bulk billing rates of pathology services, which mean that patients are less likely to question the need for the services because they do not have to pay for them. Data show that for every 100 consultations requested by medical practitioners, 25.2 pathology tests are ordered.[66]

Different futures?

The Steering Committee did not undertake a thorough review of the different ways in which pathology funding arrangements might change and thus impact on the requirements for regulation. However, it considered that it would be useful to sketch out some of the different approaches which might emerge in order to illustrate the proposition that the current legislation and regulation fit within a

65 Vining R & Mara P (1996). *General Practitioners and Pathology — the Key to Pathology Reform*. Prepared for the General Practice Branch, Commonwealth Department of Health and Family Services, Canberra.

66 General Practice Statistics and Classification Unit (1998) *Pathology Ordering by General Practitioners in Australia*. Report to the Commonwealth of Department of Health and Aged Care, Canberra.

specific set of framework arrangements which could change in a number of different ways.

Different remuneration arrangements for medical and technical services

Advances in technology in the pathology industry have seen a large number of pathology services become mechanised and automated. This has led to an increasing role for technical/scientific staff in the processing of high volume, highly automated assays.

Separating the medical and technical components of the testing would recognise the different levels of training and expertise required to perform and supervise different types of testing, interpret results and consult with clinicians. Under this scenario, if services performed by pathologists could be separated from those performed by technical and scientific staff, there would be the potential for two forms of payment:

- continuation of the current benefit arrangement for pathology services subject to detailed input by the pathologist; and
- where detailed input from the pathologist is only required for outlying results, continuation of benefit arrangements for the pathologist input but a separate direct service payment for the automated test from the Commonwealth to the APA.

Different arrangements for collection services

Collection arrangements could be opened to competitive tender. The tender could incorporate geographic restrictions (eg franchise areas) or apply to the whole of the market. Similarly, the tender could be run on a fixed fee for servicing an area or region, or a fee for service basis. In order to provide more efficient collection services and to prevent the ownership of ACCs being a barrier to entry to new pathology providers, alternative collection arrangements could be introduced.

Alternatively, general practitioners could be encouraged to provide specimen collection services for their patients and would be eligible to receive a Practice Incentive Program type payment if they did. The payment could be used either to reimburse the longer consultations required for collection of specimens, or for employment of a nurse within the practice to collect specimens. The general practitioner could decide to provide all aspects of the collection service him or herself (such as organising for a courier to transport specimens to a laboratory or taking specimens from patients in nursing homes) or the general practitioner could decide to pay an APA or a courier service.

Tendering for pathology services

To increase competition in the market and to increase the cost effectiveness of the Commonwealth's funding for pathology services, tendering for pathology services could be considered.

There are two main ways in which a tender process could work. The Commonwealth could contract pathology services directly through APAs on the basis of competitive bids; or it could seek tenders from an independent purchasing authority to purchase pathology services on its behalf.

The Commonwealth's tender could be directed at all APAs. APAs could tender on the basis of providing pathology services to standard geographical regions within Australia. As data is readily available on the number of pathology services currently provided on a national, State and regional basis, demand should be able to be predicted in certain regions. Services could be tendered on a fee for service basis or per capita. APAs could tender individually or they could group together to provide a more comprehensive service.

Alternatively, the Commonwealth could tender out the purchasing of pathology services to an independent purchasing authority. This would ensure that the Commonwealth is able to secure the best price for the services, as well allowing the Commonwealth to stipulate a number of contract conditions as mentioned above. Placing a third party between the ordering practitioner and the pathology provider may address some of the difficulties that have arisen through the vertical integration of medical companies. As the link between the orderer and provider would be removed, the problems of inducements and advertising to increase demand would be addressed. This removal of the link between the orderer and the provider may also have the potential to introduce further competition into the market and would be likely to diminish or remove the need for regulation targeted at the orderer/provider link.

Single funding arrangement for Commonwealth and State pathology

To address the competitive neutrality issues that currently exist between the public and private sectors, and to eliminate inefficiencies that have arisen from funding pathology through two health systems, the Commonwealth and States could agree to jointly fund the pathology services they require through a combined funding arrangement. A number of submissions stated their support in principle for the idea of developing a single funding pool for Commonwealth and State pathology to address the inequities between the public and private sectors.[67]

Budget holding

An alternative approach to limiting growth in pathology outlays to the current industry-wide agreements would be to provide fixed pathology budgets either to pathology providers or to doctors.

If pathology providers were the budget holders, the amount provided to them could be calculated on the basis of the number of doctors serviced and the value of the services requested by these doctors.

All doctors would be required to contract with a pathology provider for all pathology needs over a specified period, say one year.

Contracts would require the providers to render, or arrange the provision of, all services requested by a contracting doctor. Contracts would be renewed every year, at which time any doctor dissatisfied with the current level of service would be able to change pathology providers. Competition would therefore be on service levels rather than on maximising the amount of requests as at present. Because

67 1, 4, 19, 25

payment would be capped, providers would have a strong incentive to manage referrals better.

This option reverses the current incentives structure for built in growth, by providing an incentive for providers to discourage excessive or unnecessary ordering of tests and duplication of testing.

The Commonwealth could pay the funds directly to the pathology provider, and by removing the need to deal with the individual ordering patterns of doctors, this option should simplify the administration of pathology funds.

If general practitioners were the budget holders, then funds would be provided to the requesting practitioner, rather than the pathology provider. By shifting the recipient of the funds, the incentives for ordering would be reversed so that the general practitioner would be responsible for managing their own ordering within the capped allocation.

Less radical approaches would be to provide clinicians and pathologists with a financial incentive to actively participate in discussions on quality use of pathology or focus on quality use of pathology initiatives in general practice divisions, with some benefit to flow to divisions if, as a result, outlays fall.

Submissions provided comments on many of the proposed alternative funding arrangements with each specific suggestion generating a different balance of positive and negative comments. Views differed between respondents, however, a number of submissions commented that if different arrangements were to be introduced for the future funding of pathology services then wide consultation, with different players in the system, would be important.

Recommendation 18

- If there are substantial changes to the basis on which pathology services are funded by the Commonwealth, then the nature of legislation and regulation to complement the new arrangements would need to be reassessed.

Appendices

Appendix 1 - Terms of reference of the Review of Commonwealth legislation for Pathology Arrangements under Medicare

The Commonwealth legislation that relates to the provision of pathology services under Medicare ('the legislation') [see Appendix 4], are referred to the Pathology Legislation Review Committee for inquiry and report to the Minister for Health and Aged Care by 31 December 2000.

1. The Pathology Legislation Review Committee is to:

   A. Identify and describe the nature and the magnitude of the social, environmental, economic and other issues that the legislation seeks to address;

   B. Clarify the objectives of the legislation;

   C. Identify the groups likely to be affected by the legislation;

   D. Identify and set out any alternative mechanisms that may be available to achieve the objectives of the legislation, as identified in 1B, and the groups likely to be affected by the alternatives;

   E. For the legislation and its alternatives analyse and where possible, quantify the costs, benefits and overall impact on these groups including:

      i) administrative processes that are required;

      ii) quality reference standards established;

      iii) compliance costs associated with meeting the various requirements; and

      iv) any aspects which restrict competition;

   F. If new problems have become apparent, assess these problems in accordance with the regulatory best-practice requirements;

   G. Prepare a report in relation to the legislation in light of the inquiry conducted, which includes but is not limited to:

      i) recommendations relating to the legislation and its impact on the relevant groups identified in 1C & 1D above;

      ii) an outline of the basis for any recommendation which relates to quality reference standards in the legislation;

      iii) a preferred framework for regulation, if any, in light of the objectives set out in 1B;

      iv) a list of the individuals and groups consulted during the Review and an outline of their views, or reasons why consultation was inappropriate; and

v) mechanisms for increasing the overall efficiency, including minimising the compliance costs and paper burden on small business, of the legislation relating to pathology and, where it differs, the recommended framework.

2. In undertaking this inquiry and preparing the report, the Pathology Legislation Review Committee shall have regard to:

A. The broader intentions and policies of the Commonwealth Government in relation to the provision of health services to ensuring that all Australians have access to appropriate, cost effective, quality care based on need;

B. Developments in communications and information technology and their potential in terms of the provision of pathology services under Medicare;

C. In respect of the pathology industry (now and in the future) including:

i) compliance costs (including the paper work burden on small business) should be reduced where feasible;

ii) opportunities to improve administrative requirements to provide for compliance needs and business processes to be coordinated where possible; and

iii) approaches which assist the pathology industry to operate within a capped expenditure environment.

D. The broader policy objectives of the Commonwealth Government in relation to competition policy:

i) legislation/regulation which restricts competition should be retained only if the benefits to the community as a whole outweigh the costs and if the objectives of the legislation/regulation can be achieved only by restricting competition;

ii) consideration should be given, where relevant, to effects on the environment, welfare and equity, occupational health and safety, economic and regional development, consumer interests, the competitiveness of business including small business, and efficient resource allocation;

iii) the need to promote consistency between regulatory regimes and efficient regulatory administration, through improved coordination to eliminate unnecessary duplication;

iv) the analytical requirements for regulation assessment by the Commonwealth, including those set out in the Competition Principles Agreement.

3. The Review committee is to advertise nationally, consult with key interest groups and affected parties, and publish a report following Ministerial clearance.

4. In undertaking the Review and preparing its report and associated recommendations, the Review committee is to note the Government's intention to announce its responses to the recommendations, after obtaining advice from the Minister and, where appropriate, after consideration by Cabinet.

Appendix 2 - Membership of the Steering Committee

Chair

Mr David Borthwick (from February 2000 to June 2001)
Deputy Secretary
Commonwealth Department of Health and Ageing

Dr Louise Morauta (from July 2001- August 2002)
A/g Deputy Secretary
Commonwealth Department of Health and Ageing

Mr Philip Davies (from September 2002)
Deputy Secretary
Commonwealth Department of Health and Ageing

Members

Mr John Jepsen (from February 2000 to July 2002)
General Manager
Structural Reform Division
Commonwealth Department of the Treasury

Dr Paul Grimes (from August 2002)
General Manager
Budget Policy Division
Commonwealth Department of the Treasury

Ms Christianna Cobbold
Assistant Secretary
Health Capacity Development Branch
Commonwealth Department of Health and Ageing

Appendix 3 – Submissions made on the draft report

NUMBER	NAME	ORGANISATION
1	David Weedon	President, Royal College of Pathologists of Australasia
2	Jonathan Bentley	Chair, Standards & Accreditation Committee, Eastern Sydney Divisions of General Practice
3	Confidential	
4	Tony Sherbon	CEO, Illawarra Health Service
5	Matthew Cohen	APA & APP in Cat M laboratory
6	David Kindon	CEO, Aust Assoc of Pathology Practices (AAPP)
7	Vince Murdolo	Director, Bendigo Health Care Group
8	Jan Noble	Exec Officer, Aust Institute of Medical Scientists
9	Edwina Duhig	Anatomical pathologist
10	Adrian Cachia	Skin & Cancer Foundation Australia
11	Jonathan Cohen	Practitioner Cat M laboratory
12	John MacMillan	Director, Queensland Government
13	Jim Birch	Chief Executive, Dept of Human services SA
14	David Bradford	Australasian College of Sexual Health Physicians
15	P W Allen	Flinders Medical Centre, SA
16	Lindsay Dunstone	Goulburn Valley Health
17	Vicki Taylor	Executive Officer, Central Aust Division of Primary Health Care Inc
18	Peter Robertson	Hospital scientists in NSW pathology laboratories
19	Keith Shilkin	CEO, PathCentre, WA
20	Dr Anne Brand	Office of the Director, Hospitals and Ambulance Service
21	Wendy Phillips	Exec Director, Pharmacy Guild of Australia
22	Brian Curren	Rural Doctors Association of Australia
23	Wyndam Timmins	National Coalition of Public Pathology (NCOPP)

24	Joe Kelly	Lead Organiser Health, Qld Public Sector Union (QPSU)
25	A G Hayes	Deputy Director General, Queensland Government
26	Alison Killen	OATSIH
27	Ken Sikaris	Pathologist, Heidelberg Victoria
28	Louise Smyth	Pathologist
29	B Vernon-Roberts	Institute of Medical & Veterinary Science
30	Bruce Sunderland	School of Pharmacy, Curtin University of Technology
31	Wendy Munckhof	Australasian Society for Infectious Diseases
32	Confidential	
33	G McCaughan	Royal Prince Alfred Hospital
34	Fran Paterson	Office Manager, Manly Warringah Division of General Practice
35	Mike Daube	Director General, Dept Health WA
36	Denis Redmond	Registrar, Pathology Services Accreditation Board
37	Geoff Stonehouse	Dept of Veterans' Affairs
38	Dr T B Lynch	Pathologist
39	John O'Dea	Australian Medical Association Ltd (AMA)
40	Helen Hopkins	Consumers' Health Forum

Appendix 4 - Legislation for the regulation of pathology services in Australia

Primary legislation

Health Insurance Act 1973

Part I

3(5A), 3AA, 3C, 4A, 4B, 4BB, 4BC

Part II

16A, 19A, 19B, 19DB

Part IIA

23DA, 23DB, 23DC, 23DD, 23DDA, 23DE, 23DF, 23DG, 23DGA, 23DH, 23DK, 23DKA, 23DL, 23DN, 23DNA, 23DNAAA, 23DNB, 23DND, 23DNE, 23DNF, 23DNG, 23DNH, 23DNI, 23DNJ, 23DNK, 23DNL, 23DO, 23DP

Part V

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Part VB

124B, 124E, 124EB, 124FA, 124FB, 124FC, 124S

Part VII

129AA, 129AAA, 133

Health Insurance (Pathology Fees) Act 1991

Health Insurance (Approved Pathology Specimen Collection Centres) Tax Act 2000

Delegated legislation

Health Insurance Regulations 1975

2, 9A, 13, 16A, 17, 18

Health Insurance Commission Regulations 1975

3A, 3C, 3M

Health Insurance (Pathology Services) Regulations

Health Insurance (1999-2000 Pathology Services Table) Regulations 1999

Health Insurance (Accredited Pathology Laboratories - Approval) Principles 1999

Health Insurance (Eligible Collection Centres) Approval Principles 2001

Acronyms and abbreviations

the Act	*Health Insurance Act 1973*
ALRC	Australian Law Reform Commission
APA	Approved Pathology Authority
ACC	approved collection centre
APL	Accredited Pathology Laboratory
APP	Approved Pathology Practitioner
the Department	Commonwealth Department of Health and Ageing
HIC	Health Insurance Commission
LCC	licensed collection centre
MBS	Medicare Benefits Schedule
MPRC	Medicare Participation Review Committee
NATA	National Association of Testing Authorities
NPAAC	National Pathology Accreditation Advisory Council
ORR	Office of Regulation Review
PCC	Pathology Consultative Committee
PEI	patient episode initiation
PoCT	point of care testing
PST	Pathology Services Table
PSTC	Pathology Services Table Committee
RCPA	Royal College of Pathologists of Australasia

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