EXPLANATORY STATEMENT

HEALTH INSURANCE ACT 1973
SECTION 23DNBA(4)

HEALTH INSURANCE (ELIGIBLE COLLECTION CENTRES) APPROVAL PRINCIPLES 2010

Subsection 23DNBA(4) of the *Health Insurance Act 1973* (the Act) requires the Minister to determine principles to be applied by the Minister in granting approvals for eligible pathology specimen collection centres under subsection 23DNBA(1) of the Act.

Under subsection 16A(5AA) of the Act, in order for medicare benefits to be payable for pathology services rendered, pathology specimens must be collected in an approved eligible collection centre (ACC), or in other specified circumstances. ACCs are currently regulated under arrangements set out in the *Health Insurance (Eligible Collection Centres) Approval Principles 2008* (the 2008 Principles).

The *Health Insurance (Eligible Collection Centres) Approval Principles 2010* (the Principles) replace the 2008 Principles. The Principles differ from the 2008 Principles in the following key respects:

- All provisions concerning the methods for determining the maximum number of approvals that may be granted to an approved pathology authority have been removed. This includes deleting the whole of Parts 3, 4, 5 and 6 of the 2008 Principles. The deletion of these provisions will remove the current limits on the number of approvals of eligible collection centres that the Minister may grant to an approved pathology authority.
- Section 6 of the 2008 Principles specified the period within which an application for approval of an eligible collection centre should be lodged and the consequence of making a late application. This provision is no longer relevant and has been deleted, as applications can be made and approvals granted at any time during the year.
- Section 28 of the 2008 Principles provided that the Minister may delegate his or her powers and functions under the Principles to the Chief Executive Officer ('CEO') of Medicare Australia. The powers that the Minister may exercise under the Principles replicate powers that the Minister may exercise under the Act. Given that subsection 131(1) of the Act enables the Minister to delegate his or her powers under the Act, section 28 of the 2008 Principles is not necessary and has been deleted. The Minister's functions under the Principles have been conferred on the CEO of Medicare Australia pursuant to the *Medicare Australia Act 1973*.

The changes to the 2008 Principles to remove the restrictions on the number of approvals of eligible collection centres that may be granted to an approved pathology authority were developed through internal-to-government Budget processes and have reached the form of the current proposal as a result of a Cabinet decision. These processes were Budget-in-Confidence and thus stakeholders could not be engaged in them. However, submissions to the 2009/10 Budget emerged from a Strategic Review of Pathology and Diagnostic Imaging Services conducted by an Interdepartmental Committee comprising the Department of Health and Ageing, the Department of Finance and Deregulation, the Department of the Prime Minister and Cabinet and the Treasury in 2007-08. This Review included broad and extensive consultation with key stakeholders, including the Royal College of Pathologists of Australasia, the National Coalition of Public Pathology and the Australian Association of Pathology Practices. Approximately 30 submissions were received and considered.

The Principles commence on 1 July 2010.

Details of the Principles are set out in Attachment A. A statement on the regulatory impact of the removal of the restriction on the number of approvals of eligible collection centres that may be granted to an approved pathology authority is at Attachment B.

The Principles are a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

ATTACHMENT A

NOTES ON SECTIONS OF THE PRINCIPLES

Part 1 Preliminary

Section 1 Name of Principles
This section provides that the Principles may be cited as the *Health Insurance (Eligible Collection Centres) Approval Principles 2010.*

Section 2 Commencement
This section specifies the commencement date of the Principles as 1 July 2010.

Section 3 Definitions
This section defines key terms used in the Principles.

Part 2 General principles for applications

Section 4 Eligibility of premises for approval
This section specifies the criteria that the eligible specimen collection centre must meet before an application for approval of an eligible collection centre can be considered by the Minister.

Section 5 Application for approval
This section specifies the criteria to be met before an application for approval of an eligible collection centre can be considered by the Minister. For example, the applicant must be an approved pathology authority (APA):

- who operates a category G pathology laboratory in certain circumstances (see paragraphs 5(2)(a) and 5(2)(b)); or
- who operates a category S pathology laboratory in certain circumstances (see paragraph 5(2)(c)).

Section 5 also provides that an application must be made in the prescribed form and specifies the documentation to be provided in support of an application (see subsections 5(1) and 5(3)).

Section 6 Approvals
Subsection 6(1) specifies the commencement of an approval to be on the day approval is granted or, where a day is specified in the approval, on that day. Subsection 6(2) specifies that the commencement date of an approval may be backdated in special circumstances. Subsection 6(3) specifies that an approval must be expressed to be valid for one year. Subsection 6(4) specifies that the Minister will give to an applicant written notice of the decision to grant, or not to grant, an approval and if the decision is to not grant approval or backdate commencement as requested, the applicant's right to have the decision reconsidered.

Part 3 Other Matters

Section 7 Compliance with the Collection Centre Guidelines
This section deals with the giving of an undertaking by an APA under paragraph 5(3)(a) of the Principles. This undertaking must include an undertaking that the APA will inform Medicare Australia of any failure to comply with the Collection Centre Guidelines in operating an approved collection centre and provide a reason for the non-compliance.

Section 8 Review of decisions

Subsection 8(1) specifies the time-frame within which the Minister must respond to an application for reconsideration made under subsection 23DO(2DA) of the Act.

Subsection 8(2) provides that an applicant who is dissatisfied with the Minister's decision under paragraph 5(3)(a) of the Principles (under that provision, the Minister can accept that compliance with some, or all, provisions of the Collection Centre Guidelines is not reasonably practicable) may apply to the Administrative Appeals Tribunal for review of the decision.

The note to this section also refers to the Code of Practice created under section 27B of the *Administrative Appeals Tribunal 1975*, which is accessible on the Internet at: http://www.comlaw.gov.au

Part 4 Transitional

Section 9 Transitional

This section provides that the Principles will apply to an application for approval made in relation to a period after 1 July 2010, even where the application is made prior to 1 July 2010. This enables applications before the Minister at 1 July 2010 to be considered under the Principles.

ATTACHMENT B

REGULATION IMPACT STATEMENT

Rationalising Patient Episode Initiation Fees and Reducing Regulation on Pathology Collection Centre Eligibility

1. Background and Problem

The government has requested the Departments of the Prime Minister and Cabinet, Treasury, Finance and Deregulation, and Health and Ageing (DHA) to undertake a strategic review to examine the future funding arrangements for diagnostic imaging and pathology as part of the second stage of an expenditure review. The context of the review included the broader fiscal policy of the government in relation to government outlays, with a focus on fiscal sustainability. The terms of reference for the review require it to examine whether the current resources available for delivering pathology services are used in the most efficient manner to achieve high quality services, which are clinically appropriate and maintain patient safety, and if there are better ways to do so. The review was also to specifically consider whether alternative arrangements would result in more efficient service provision, providing value for money and the capacity within the pathology sector to minimise overheads.

The pathology industry

Private Sector Pathology

In the early 1980s, private pathology laboratories were mainly owned and operated by practicing pathologists and offered a limited range of services over a limited geographic area. Divestment of ownership was usually to associates (with a view to future equity) and the acquisition was usually funded from profit distributions to the retiring equity holder. The cost of equity was relatively low in order to be affordable. Changes allowed incorporation of professional practices, significantly changing the value of equity and opened the way for wider divestment.

By the 1990s, new technology was starting to have an impact on the practice of pathology, as automation replaced labour for the performance of many routine tests. Technological improvement allowed more tests to be performed more efficiently in a single laboratory and created the initial impetus for greater industry consolidation. Price pressures sped up the rate of industry concentration by making the identification and realisation of efficiencies more urgent. These pressures encouraged mergers and acquisitions to create larger enterprises more able to take advantage of the increased capacity of emerging technologies and the more rational use of scientific and technical staff. Eventually, only large, publicly listed corporations, usually with health industry experience, could raise the capital to further aggregate pathology enterprises and produce the industry structure that we have today.

The Australian Competition and Consumer Commission (ACCC) has developed generic industry concentration thresholds to evaluate merger proposals to determine whether the merger would have a significant adverse impact on industry competition. The ACCC considers that problems in competition occur when the top four industry stakeholders hold a concentration of 75 per cent or more of industry sales or where one firm holds more than a 15 per cent of the market. Ibisworld estimates that the four largest players account for about 94 per cent of pathology

industry revenue, with the top two players owning 40 per cent and 38 per cent respectively – well above the thresholds identified by the ACCC.

Public Sector Pathology

Public laboratories, with some significant exceptions, had no outreach and largely provided laboratory services to public hospitals. The exceptions were the State Health Laboratories of Western Australia and in South Australia whose governments have underwritten the rural outreach of these laboratories. The other feature of public laboratories has been their operation as reference laboratories for rarer and more expensive analyses.

The public sector has been largely funded by historical budgeting which has also been restrained within the limits of growth of hospital funding by the states. However, the increased 'privatisation' of out-patient services has created an opportunity to develop a more significant Medicare income stream. Some states have aggregated their laboratories into networks or separate institutions in order to parallel the efficiencies of the private sector and to minimise the costs of duplication. The same technology drivers that forced concentration in the private sector are increasingly having the same effect in the public sector.

Regulatory Problem: Collection Centre Numbers

Under existing regulatory arrangements for pathology, in order for Medicare benefits to be payable, a pathology service must be performed by, or on behalf of, an Approved Pathology Practitioner (APP) in an Accredited Pathology Laboratory (APL) which is owned and/or operated by an Approved Pathology Authority (APA). Specimens collected for Medicare-eligible pathology testing can be collected from the patient by the treating practitioner or by the APP (or someone collecting the specimen on their behalf), or by the patient themself. There are a number of locations where a specimen can be collected including the patient's residence, a medical practice, a hospital, a nursing home, or at an Approved Collection Centre (ACC), which is owned and/or operated by an APA.

The Licensed Collection Centre (LCC) scheme was implemented in 1992 to address concerns that there were too many collection centres operating in the industry, leading to inefficiencies and increased costs to Medicare and the community. The scheme aimed to reduce the number of collection centres by limiting the number of LCCs that a pathology provider could operate. Under the LCC scheme, new providers were initially allocated two external collection centre licences for each new laboratory for the first two years of its operation. To be allocated additional licences thereafter a provider must have had at least 14,200 patient episodes per year. If providers did not attain the required number of episodes per year per licence after their initial two years of operation, or at any point thereafter, they lost their external licence entitlement and capacity to grow their businesses.

This allocation framework was considered a significant barrier to entry for new entrants because:

- two collection centres were significantly lower than what was required to operate an economically viable business – estimates are that 10 collection centres are required to be economically viable and that 5 would be a breakeven point;
- two years is too short a time to develop sufficient throughput to compete on equal grounds with other more established providers;
- given the capital intensive nature of laboratories there are significant start up costs requiring longer payback periods – potential entrants require a longer period of certainty to justify the business case for entry;

- the '14,200' rule did not reflect the evolving nature of the market and the profession – the number represented the ratio of MBS episode activity to allocated units of entitlement as at 1 July 2001; and
- the number was not an accurate reflection of the average throughput of a collection centre – the average throughput of a collection centre is in the vicinity of 6,000 patient episodes per year.

In 2001, the pathology industry and the Australian Government entered into negotiations to establish a new allocation framework, under the ACC scheme, the maximum number of ACCs an APA may operate was dependent upon:

- the category of the APL it operated;
- the length of time it had operated the APL; and
- the number of patient episodes the APA provided a pathology service during the relevant calendar year – for every 14,200 episodes an APA obtains an additional licence to operate another collection centre.

In 1995, the Commonwealth and the States agreed to implement National Competition Policy (NCP) reforms. The inter-governmental *Competition Principles Agreement* (CPA), provides a commitment to ensure that new and existing legislation does not impose undue restrictions on competition. The regulation of pathology collection centres was identified as an area where possible undue impediments to competition may exist and a review of the regulation was undertaken.

The KPMGs 2006 *Review of Current Arrangements for Regulation of Approved (Pathology) Collection Centres* followed the principles laid down in the CPA. KPMG considered that the framework inhibited the growth of smaller providers while facilitating the growth of larger providers, hence it created an uneven playing field, and recommended that, based on NCP principles, there should be no allocation method for collection centre licences.

Changes to the ACC scheme came into effect in 2007 to address some of the issues raised in the KPMG report. Although the rules for allocation of collection centre numbers changed, government regulation on the allocation of collection centre numbers was not removed. Under the *Health Insurance (Eligible Collection Centres) Approval Amended Principles* 2007 (the Principles), smaller providers are now entitled to a minimum of four ACCs, growing by one additional ACC each year. To restrain aggregate growth in ACCs, growth for providers with more than four ACCs is restricted to one additional ACC, or an increase equivalent to the rate of population growth, whichever gives the highest result. The Principles support small providers with a 'floor' of four ACCs but otherwise do not discriminate between providers according to their size. There is scope under the new scheme for the aggregate number of ACCs to increase at the rate of population growth at a minimum. It is this provision in the Principles, however, that inequitably restricts the medium sized players' capacity to grow in the short term.

There has been a clear trend of increasing numbers of collection centres and greater concentration of ownership. The number of collection centres has increased from 1427 to 2200 today (ie 54 per cent) since the ACC scheme was introduced in 2001, with the four largest private operators owning approximately 80 per cent of collection centres. Collection centre ownership by the smaller private operators (ie about 150 providers) has decreased from 55 per cent to around 18 per cent. Flaws in the mechanisms for allocating collection centre licences have contributed to the concentration in ownership of collection centres. Further concentration may result in there being less incentive for the industry to compete on price and convenience for patients, inevitably leading to increased prices for Government and consumers.

Patient Episode Initiation Fees

In 1992, the former twin Medicare Benefits Schedule (MBS) fee tables for public and private pathology operations were replaced by a single uniform table effective for both public and private operations. Before this, private operators were eligible for a higher rebate than public operators, on the grounds that public laboratories were subsidised by government in terms of overheads and capital outlays. The change to a single table equivalent to the former public rates table meant a drop in rebates per service of around 30 per cent for private operators.

At the same time, a new MBS item was introduced for private pathology providers, known as the Patient Episode Initiation (PEI) fee, to offset the potential loss of income by private operators from the revision of schedule fee tables. PEI fees are a means of separating test costs from operating costs such as the overhead costs of the specimen collection centre, staff and equipment, transport costs between the patient, the collection centre and the laboratory, storage facilities, and quality control and licensing. Previously, each MBS pathology test item had an overhead cost component which meant pathology practices were reimbursed several times for expenses incurred in relation to the processing of a single specimen when several tests were requested. The PEI fee is payable only once in a patient episode (ie it can only be claimed once per patient per day), regardless of how many tests are requested in that day. Four different PEI fee levels were introduced, with the location or manner of collection serving as a basis for the different fee levels.

It is now common practice for public sector laboratories to accept private work and to operate as independent business units that pay a hospital, state or territory for the infrastructure they use. In recognition of this, patients who provide specimens for pathology testing through a public pathology provider are now eligible to receive a PEI rebate, albeit at a significantly lower rate than rebates paid for private operators.

There are currently twenty PEI fees with eight different fee levels, ranging from $2.40 to $17.70, depending upon where the specimen is collected and whether the provider is in the public or private sector. Services initiated at privately operated collection centres, hospitals and aged care facilities receive the highest rebates while the lowest rebates are the PEI fees that can be claimed by public sector pathology providers. The differential in PEI rates for collection centres provides an incentive for practices to channel specimens through collection centres and shift away from other collection environments.

In 2007-08 PEI benefits accounted for 18 per cent of total pathology expenditure, with 65 per cent of PEI expenditure being channelled through collection centres. On average, PEI revenue for the four largest operators for specimens channelled through collection centres accounted for approximately 14 per cent of their total MBS pathology revenue. Industry's attraction towards collection centres would suggest that the PEI fee for collection centres is more than adequate to cover overheads and 'abnormal' profits may be attributed to the government setting fees too high.

2. Objectives

The objectives for government are to ensure that Australians have access to high quality, clinically appropriate and affordable health care services by:

- ensuring the financial sustainability of Medicare; and
- encouraging a sustainable, competitive and an efficient pathology industry.

3. Options

Option A: Retain the current range of payments for the collection of pathology specimens and the current restrictions on eligibility for collection centres.

Option B: Introduce a two-tier PEI fee structure depending on whether the services are provided by a public or a private operator. Under this option, the current PEI fee of $2.40 for public operators would be retained, and for private operators, a flat rate of $6.00 would be introduced. In addition to the adjustment to the PEI fees, the current restrictions on the number of collection centres for Medicare-eligible pathology specimens a pathology provider can operate would be removed.

Option C: As for option B. However, under this option, the PEI fee structure would be $4.00 for public operators and $6.00 for private operators.

Option D: Introduce a five-tiered PEI structure. The PEI fee structure for public operators would be $2.40 for a patient billed episode or $4.00 if bulk billed. For private operators, the PEI fee would be $6.00 for a patient billed episode or $10.60 for a bulk billed episode, apart from episodes where the specimen is collected at a Residential Aged Care Facility, where the fee would be $17.00. As for Options B and C, the restrictions on collection centre numbers would also be relaxed under this option.

Table 1 at Attachment A compares the PEI fees proposed under each option.

4. Impact Analysis

The measure will impact on the following stakeholder groups:

- Australian Government
- pathology providers
    - state and territory government organisations (public providers)
    - large privately operated practices
    - small privately operated practices
- consumers

The expected impacts of each option are discussed below.

Option A

Australian Government

Cost
The necessary savings in pathology expenditure would not be achieved.

Benefits
There would be no benefits to the Australian Government arising from this option as the problems would not be addressed.

Public pathology providers

This option would have no impact on public providers.

Large private pathology providers

This option would have no impact on large private providers.

Small private pathology providers

Cost
The current distortion in the marketplace would continue as the problems associated with the allocation of collection centre numbers would not be addressed.

Benefits
There would be no benefits for small private pathology providers arising from this option.

Consumers

Cost
This option may impact on the long-term viability of Medicare-funded health services, resulting in poor health outcomes for patients.

Benefits
There would be no disruption to pathology services in the short term.

Option B

Australian Government

Cost
The magnitude of the fee reductions may force providers to cease bulk billing patients or increase co-payments, possibly impacting on government expenditure under the Medicare Safety Net. The Medicare Safety Net protects patients against high out-of pocket expenses. Under the safety net, Medicare rebates 80 per cent of out-of-pocket expenses for non-admitted services, once certain thresholds are reached. Concession cardholders, families receiving Family Tax Benefit, and families that qualify for notional Family Tax Benefit are eligible for the extended safety net when their cumulative out-of-pocket expenses reach $529.30; all other singles couples and families are eligible when their cumulative out-of-pocket expenses reach $1,058.70. It would not be uncommon for patients with chronic conditions requiring frequent pathology testing to reach the safety net thresholds.

Private pathology providers would be unhappy with the measure and may publicly oppose the decision. It will be essential for the Department to work in close consultation with the pathology profession during the proposed review of the Pathology Services Table. The pathology profession may be uncooperative during the course of the review in reaction to the decision.

Medicare Australia would incur costs of $3.3 million to implement changes relating to collection centre eligibility.

Benefits
This option would result in immediate savings to MBS pathology expenditure, allowing the government to direct funds to other priorities. It would also contribute to the long-term viability of Medicare.

Public pathology providers

This option would have no impact on public providers.

Large private pathology providers

Cost
In 2007-08 the four large private pathology providers, between them, received approximately $294 million in PEI revenue, representing approximately 20 per cent of their total revenue from MBS funded pathology services. Under this option, it is estimated that their combined PEI revenue would be reduced by approximately $170 million per annum, or 58 per cent because of their reliance on collection centre collections. This may mean that these providers would reduce the number of low-profit services that they currently provide. There may also be job losses for collection centre staff, couriers etc. and increased waiting times for patients.

As mentioned above, the four large pathology providers have enjoyed a significant competitive advantage over small operators under the current arrangements for allocating collection centre licences. The proposal to remove the restrictions on the number of collection centres that providers can operate would reduce this competitive edge.

Benefits
There would be no benefits for large private pathology providers arising from this option.

Small private pathology providers

Cost
Combined PEI revenue for 107 small private pathology providers in 2007-08 was approximately $29 million. On average, this accounted for 15 per cent of their total MBS pathology revenue. Under this option, it is estimated that their combined PEI revenue would be reduced by $15 million (ie 53 per cent), or approximately $140,000 per practice. The magnitude of these reductions may result in job losses for small practices that are unable to recover the loss of revenue by imposing or increasing patient co-payments, for example those located in low socio-economic areas. In some cases, it could result in practice closures.

Benefits
Removing the restrictions on the number of collection centres may place smaller operators on a level playing field, possibly reducing the current distortion in collection centre ownership.

Consumers

Cost
Patients who provide a specimen through a private provider's collection centre would receive a reduced rebate. Providers may seek to reduce bulk billing or increase patient co-payments. Those patients who require ongoing testing to manage chronic conditions, and are least able to afford co-payments, are more likely to be non-compliant and forego necessary pathology services.

Benefits
Deregulation of collection centre numbers may encourage competition, creating greater patient choice of provider.

Option C

Australian Government

Cost
This option would reduce the savings expected under Option B. Other costs would be similar to those under Option B.

Benefits
This option would still achieve significant savings to government.

Public pathology providers

Cost
There would be no negative impacts for public sector providers arising from this option.

Benefits
In 2007-08, combined PEI revenue for public providers was approximately $6.2 million. This option could increase their PEI revenue by about $3 million.

Large private pathology providers

The impacts under this option would be as for Option B, although to a lesser extent.

Small private pathology providers

Cost
The cost impacts under this proposal are as for Option B, although the loss of MBS revenue under this option would not be as high.

Benefits
Under the current fee structure, the PEI fee for specimens collected at a collection centre that is co-located with the provider's laboratory is $2.40. The proposed PEI rebate would increase from $2.05 to $5.60 (ie 273 per cent) . This would benefit smaller providers who gain a greater proportion of specimens through co-located centres.

Consumers

The impacts of this option are as for Option B, although to a lesser extent.

Option D

Australian Government

Cost
Savings to MBS pathology expenditure would be lower than under Options B and C. Medicare Australia would incur costs of around $3.3 million to implement the measure.

Benefits
Savings to MBS pathology expenditure would still be substantial under this option. This option would be more acceptable to stakeholders than Options B and C, given that the bulk billing incentive would result in increases to some rebates.

Public pathology providers

Bulk billing rates for public sector providers are high. Increasing the PEI to $4.00 for bulk billed services would increase PEI revenue by about $3 million a year if they retain or increase their current high bulk billing rates.

Large private pathology providers

Cost
The cost to large private operators is similar to that under Options B and C, although to a lesser extent – under this option, the loss of PEI revenue for larger providers would be between 34 and 42 per cent.

Benefits
Some PEI rebates, when combined with the bulk billing incentive would increase under this option.

Small private pathology providers

Cost
The cost to small private operators is similar to that under Options B and C, although to a lesser extent – under this option, PEI revenue for smaller providers would be reduced by 27 per cent.

Benefits
Some PEI rebates, when combined with the bulk billing incentive would increase under this option:

- Under the current fee structure, the PEI fee for specimens collected at a collection centre that is co-located with the provider's laboratory is $2.40. The proposed PEI fee for private providers, when combined with the bulk-billing incentive payment, would increase from $2.40 to $10.60.
- Other sensitive collection fees, particularly for privately provided cervical cytology (Pap smears), will be increased in the case of bulk billed episodes from $8.25 to $10.60.

Private providers currently receive a higher PEI rebate when they collect pathology specimens from patients residing at an aged care facility who have limited access to community specimen collection facilities. The reduced PEI fee may discourage pathology providers from offering these services. The $17.00 PEI fee for private operators who collect specimens from patients at a residential aged care facility, and bulk bill, may encourage providers to continue to offer this service.

Consumers

Cost
The likely costs under this option are the same as for Options B and C, although to a lesser extent than under Option B.

Benefits
The reduced PEI fee proposed under Option B may discourage pathology providers from collecting specimens from patients at Residential Aged Care Facilities. The higher bulk billing incentive payment may encourage providers to continue to offer this service to those that have limited access to community specimen collection facilities.

Table 2 at Attachment B illustrates the likely costs and benefits of the policy options on each stakeholder group.

5. Consultation

Thirty-four key stakeholders responded to the IDC's call for submissions to the strategic review of future funding arrangements for diagnostic imaging and pathology, twenty-four of which provided official written submissions addressing pathology issues. These included: Medical Technology Association of Australia, Mr Mike Ralston, Dr Sydney Bell, Dr Lloyd McGuire, Australasian Society of Anatomical Pathologists, SA Health, Royal College of Pathologists of Australasia, ACT Health, National Serology Reference Laboratory, Catholic Health Australia, Royal Australian College of General Practitioners, Department of Health and Human Services Tasmania, Queensland Health, Department of Health – WA, National Coalition of Public Pathology (NCOPP), Australian Association of Pathology Practices (AAPP), Australian Medical Association, NSW Health, Australian Association of Consultant Physicians, Breast Cancer Network Australia, Human Genetic Society of Australasia, Royal Australasian College of Physicians, Consumers Health Forum of Australia, The Thoracic Society of Australia and New Zealand, and the Department of Human Services – Victoria.

While the pathology and diagnostic imaging groups showed distinct concerns, there was clear consensus amongst pathology stakeholders in the following areas:

- the assignment of benefits of a procedure should be based upon the cost of performing the test, the professional input and the risks pertaining to the service;
- automatic indexation should be applied to MBS fees for diagnostic services, as is the case with all other medical services funded under the MBS;
- PEI fees should be reviewed, particularly in relation to PEI rebates for services provided by public pathologists;
- the government should encourage bulk billing and discourage co-payments – co-payments were perceived as likely to discourage those with the greatest need from obtaining necessary medical services;
- collection centre licensing arrangements are anti-competitive and should be changed or discarded – although the AAPP does not share this view;
- where there are sweeping reforms to funding arrangements, for example moving from MBS fee for service arrangement to tendering or fee holding arrangements, changes should be introduced incrementally; and
- incentive payments or higher Medicare rebates should be implemented for practices in rural areas to encourage service provision.

During the course of the review, KPMG consulted with representatives of 36 industry stakeholders and representatives of Medicare Australia. AAPP and NCOPP provided official written submissions.

Consultations undertaken revealed that private providers are not opposed to public sector accredited laboratories having equitable access to the PEI, so long as their eligibility does not affect the current PEI payments for private pathology providers.

6. Conclusion

The Government will achieve its stated objective to ensure that Australians have access to high quality, clinically appropriate and affordable health care services through:

- targeted adjustments to Medicare rebates for pathology services; and

- moderation of the current restrictions on eligibility for a licence to operate a collection centre.

Although Option A would not disrupt the current provision of pathology services, retaining current excessive PEI rebates will affect the financial sustainability of Medicare in the long-term. This option does not address the competition problems associated with high market concentration that were identified in the KPMG review.

Rationalising the PEI fees, as proposed under Option B, would significantly reduce government expenditure on pathology services, allowing the government to redirect funds to other priorities.

However, the significant reductions in rebates under Option B would likely result in reduced bulk billing levels and increases in patient co-payments. Patients who are unable to afford co-payments are more likely to forego necessary pathology services, leading to poor health outcomes. The magnitude of the reductions may affect the future viability of pathology practices that are located in lower socio-economic areas where there is limited capacity to pass the revenue loss on to their patients.

Although Option C would reduce the level of savings in pathology expenditure, the proposed PEI fees of $4.00 and $9.00 would have a lower impact on pathology practices, discouraging some providers from passing the loss of revenue on to patients.

The impact of Option D is similar to Option C. The bulk billing fee would increase some PEI fees under the current fee structure. The bulk billing PEI incentive payable for patients of public providers should encourage public provider to sustain the current high rate of bulk billed pathology services.

Options B, C and D would encourage competition by lifting the limit on collection centre numbers, enabling both small and large providers to place collection centres in areas where they consider to be commercially viable. Reducing PEI fees for specimens channelled through collection centres will reduce the incentive for providers to establish more collection centres than are needed. These options would remove the current distortion in the pathology market, resulting in greater choice for consumers. However, the loss of PEI revenue is also likely to increase costs for patients and, depending on the level of savings, pathology providers may close those collection centres that have high overhead costs and/or low throughput. While this will reduce some barriers to entry for new competitors in the pathology sector, the economies of scale involved in some kinds of pathology testing may continue to create a barrier for smaller providers.

Option D is the preferred option as it achieves savings for the Australian Government. This option would substantially increase PEI revenue for public sector pathology providers, reduce the level of financial impact on patients and pathology practices, and reduce the risks to patient health outcomes. Option D also addresses the competition problems associated with market concentration identified in the KPMG review.

Implementation and review

It is proposed that the changes in the PEI fees will be implemented on 1 November 2009 and will result in an immediate reduction in pathology expenditure. The new PEI fees will be implemented through changes to the Pathology Services Table Regulations.

Changes to restrictions on collection centre eligibility will be implemented through amendments to the Eligible Collection Centre Approval Principles and the *Health Insurance (Approved Pathology Specimen Collection Centres) Tax Act 2000*. This element of the proposal would take effect from 1 July 2010 to allow pathology providers an opportunity to consider the impact of this change and to accommodate necessary adjustments for Medicare Australia.

The Department of Health and Ageing will regularly review MBS statistics on the number and distribution of pathology collection centres to measure the impact on the pathology industry. The Department will also review MBS data on pathology expenditure to measure the impact on patients and the delivery of savings.

Attachment A

Table 1: Comparison of MBS Rebates Options

Collection Type	2007-08 Services '000s	Option A: Retain current PEI fees		Option B: Flatten PEIs to $6.00 for private sector providers and $2.40 for private sector providers				Option C: Flatten PEIs to $9.00 for private sector proivers and $4.00 for private sector providers				Option D: Flatten PEI fees (as per Option B) combined with Bulk Billing Incentive PEI fees			
		MBS Fee $	MBS Rebate* $	MBS Fee $	MBS Rebate* $	Rebate Change $	Rebate Change %	MBS Fee $	MBS Rebate* $	Rebate Change $	Rebate Change %	MBS Fee	MBS Rebate* $	Rebate Change $	Rebate Change %
Co-located collection centre**	-	2.40	2.05	6.00	5.10	3.05	149%	9.00	7.65	5.60	273%	10.60	9.00	6.95	339%
Pap smear	1,188	8.25	7.05	6.00	5.10	-1.95	-28%	9.00	7.65	0.60	9%	10.60	9.00	1.95	28%
Tissue pathology – in-patient	557	14.75	11.10	6.00	4.50	-6.60	-59%	9.00	6.75	-4.35	-39%	10.60	7.95	-3.15	-28%
Tissue pathology – out-patient	1,357	8.25	7.05	6.00	5.10	-1.95	-28%	9.00	7.65	0.60	9%	10.60	9.00	1.95	28%
Collection centre	14,306	17.40	14.80	6.00	5.10	-9.70	-66%	9.00	7.65	-7.15	-48%	10.60	9.00	-5.80	-39%
Private hospital in-patient	1,205	17.70	13.30	6.00	4.50	-8.80	-66%	9.00	6.75	-6.55	-49%	10.60	7.95	-5.35	-40%
Home collect	851	10.30	8.80	6.00	5.10	-3.70	-42%	9.00	7.65	-1.15	-13%	10.60	9.00	0.20	2%
Aged care facility	4,181	17.70	15.05	6.00	5.10	-9.95	-66%	9.00	7.65	-7.40	-49%	17.00	14.45	-0.60	-4%
Self-collect	540	9.80	8.35	6.00	5.10	-3.25	-39%	9.00	7.65	-0.70	-8%	10.60	9.00	0.65	8%
Treating practitioner collect	6,218	9.80	8.35	6.00	5.10	-3.25	-39%	9.00	7.65	-0.70	-8%	10.60	9.00	0.65	8%
Public providers	3,138	2.40	2.05	2.40	2.05	-	-	4.00	3.40	1.35	66%	4.00	3.40	1.35	66%
Specimen referred	426	10.30	8.80	6.00	5.10	-3.70	-36%	9.00	7.65	-1.15	-13%	10.60	9.00	0.20	2%

* Relates to most common rebate of 85% for out-of-hospital episode (75% payable for in-hospital episode)

** New item added in 2008-09

Attachment B

Table 2: Likely Impacts of Policy Options

Stakeholder Group	**Option A: Retain the current PEI fees**	**Option B: Rationalise to two PEI fees – $2.40 for the public sector and $6.00 for the private sector**	**Option C: Rationalise to two PEI fees $4.00 for the public sector and $9.00 for the private sector**	**Option D: Rationalise to two PEI fees ($2.40 and $6.00) for patient billed episodes and three PEIs ($4.00, $10.60 and $17.00) for bulk billed episodes**
Australian Government	*Cost* • Necessary savings will not be achieved *Benefits* • Nil	*Cost* • Any increases to patient co-payments may impact on Medicare Safety Net • Pathology providers may publicly oppose decision • Pathology profession not willing to co-operate with Government on pathology review • Implementation costs for Medicare Australia *Benefits* • Significant savings to MBS expenditure on pathology services	*Cost* • Savings to MBS expenditure lower than under Option B. *Benefits* • Significant savings to MBS expenditure on pathology expenditure	*Cost* • Savings to MBS pathology expenditure lower than under Options B and C • Implementation costs for Medicare Australia *Benefits* • Would result in acceptable savings in MBS pathology expenditure • Option would be more acceptable to stakeholders than Options B and C given that the bulk billing incentive would result in increase to some rebates
State and Territory Government pathology providers	No impact	No impact	*Cost* • Nil *Benefits* • PEI revenue will	*Cost* • Nil *Benefits* • PEI revenue will

Stakeholder Group	Option A: Retain the current PEI fees	Option B: Rationalise to two PEI fees – $2.40 for the public sector and $6.00 for the private sector	Option C: Rationalise to two PEI fees $4.00 for the public sector and $9.00 for the private sector	Option D: Rationalise to two PEI fees ($2.40 and $6.00) for patient billed episodes and three PEIs ($4.00, $10.60 and $17.00) for bulk billed episodes
			significantly increase	significantly increase if current bulk billing levels are retained
Large Private Pathology Providers	No impact	*Cost* • Combined loss of PEI revenue of $170 million a year (58%) • Current competitive edge for collection centre ownership reduced • Possibility of job losses *Benefits* • Nil	*Cost* • As for option B, although the costs would not be as high under this option *Benefits* • Nil	*Cost* • As for Options B and C, but the costs much lower than other options *Benefits* • Nil
Small Private Pathology Practices	*Cost* • The current distortion in ACC ownership will remain *Benefits* • Nil	*Cost* • Combined PEI revenue reduced by approximately $15 million (53%) • Possible job losses – in some cases, may lead to practice closures *Benefits* • Removal of restrictions on collection centre numbers will remove current	Impacts as for Option B, but to a lesser extent	*Cost* • As for Options B and C, although loss of revenue would not be as significant for those providers who continue to bulk bill *Benefits* • Some PEI rebates will increase, when combined with the Bulk Billing incentive

Stakeholder Group	Option A: Retain the current PEI fees	Option B: Rationalise to two PEI fees – $2.40 for the public sector and $6.00 for the private sector	Option C: Rationalise to two PEI fees $4.00 for the public sector and $9.00 for the private sector	Option D: Rationalise to two PEI fees ($2.40 and $6.00) for patient billed episodes and three PEIs ($4.00, $10.60 and $17.00) for bulk billed episodes
		distortion in collection centre ownership		
Consumers	*Cost* • Risks future viability of Medicare, leading to poor health outcomes for patients *Benefits* • There will no disruption to current pathology services	*Cost* • Providers may reduce bulk billing rates or increase patient co-payments – patients least able to afford will forego necessary pathology testing *Benefits* • Deregulation of collection centre numbers may lead to greater patient choice of provider • Contributes to the long-term sustainability of Medicare	*Cost* • Similar to Option B *Benefits* • As for Option B	*Cost* • Similar to Option B, although the increases to co-payments may be less than under Options B and C *Benefits* • As for Options B and C