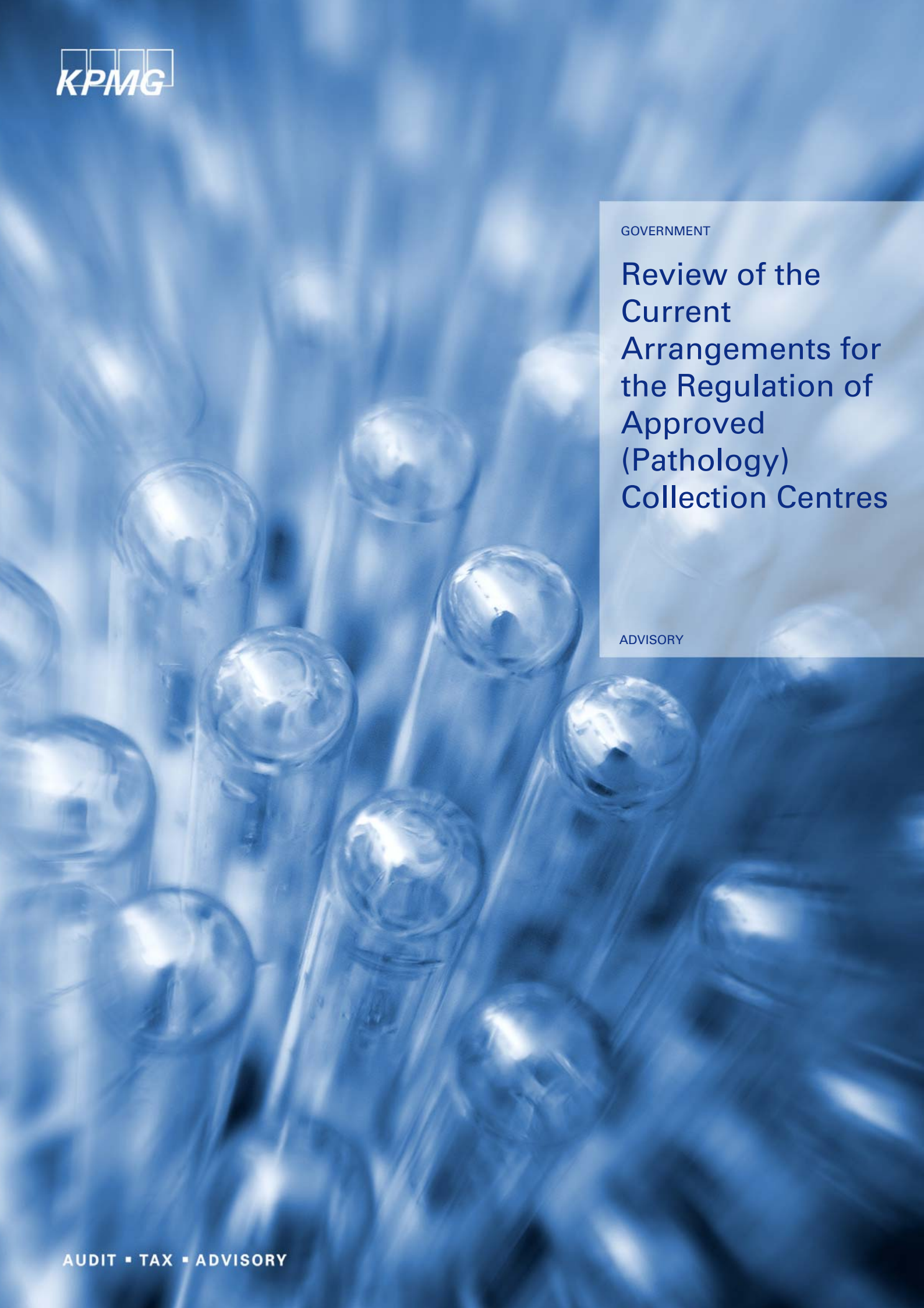

KPMG

GOVERNMENT

Review of the Current Arrangements for the Regulation of Approved (Pathology) Collection Centres

ADVISORY

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Executive summary

As part of the Australian Government's commitments under National Competition Policy (NCP), KPMG was engaged by the Department of Health and Ageing (the Department) to conduct an NCP review of the Approved (Pathology) Collection Centre (ACC) Arrangements.

The review, which has been conducted in line with the Terms of Reference (see Appendix A), follows the principles laid down in sub-clause 5(1) of the intergovernmental *Competition Principles Agreement (CPA)* which states that legislation or regulation should not restrict competition unless it can be demonstrated that:

- the benefits of the restriction to the community as a whole outweigh the costs; and
- the objectives of the legislation can only be achieved by restricting competition.

The pathology industry

Industry participants

There are generally four types of entities involved in the pathology testing process:

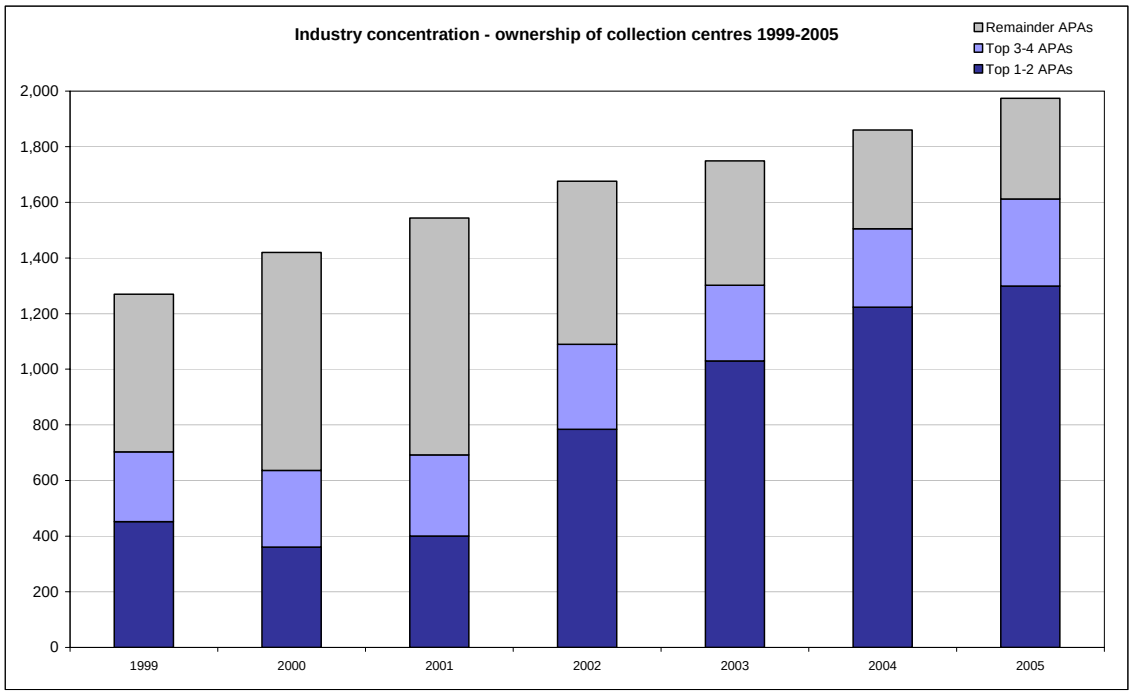
- Approved Pathology Authorities (APAs) – the entities authorised to own/operate pathology laboratories and collection centres;
- Approved Pathology Practitioners (APPs) – the medical practitioner authorised to perform pathology tests;
- Accredited Pathology Laboratories (APLs) – the premises at which pathology tests must be performed; and
- Approved Collection Centres (ACCs) – one of the locations at which a pathology specimen for testing may be collected.

This review is specifically focussed on the regulatory arrangements for ACCs.

Trends in supply and demand

The Australian pathology industry has undergone significant structural change over the past two decades, and is now dominated by a number of large corporatised entities. There has been a clear trend of increasing numbers of collection centres and greater concentration of ownership over the period 1999 to 2005, as illustrated in the figure below.

Figure 1: Ownership of collection centres, 1999 to 2005



KPMG specifically notes that the top four industry players hold a 81.7 per cent market share with the top two industry players holding market shares of 35.7 per cent and 30.1 per cent respectively.

In addition to consolidation, there is a growing trend towards vertical integration of pathology providers with large medical practices containing significant number of general practitioners and hence a large referral base, sometimes with radiology and pharmacy practices – a 'one stop shop'.

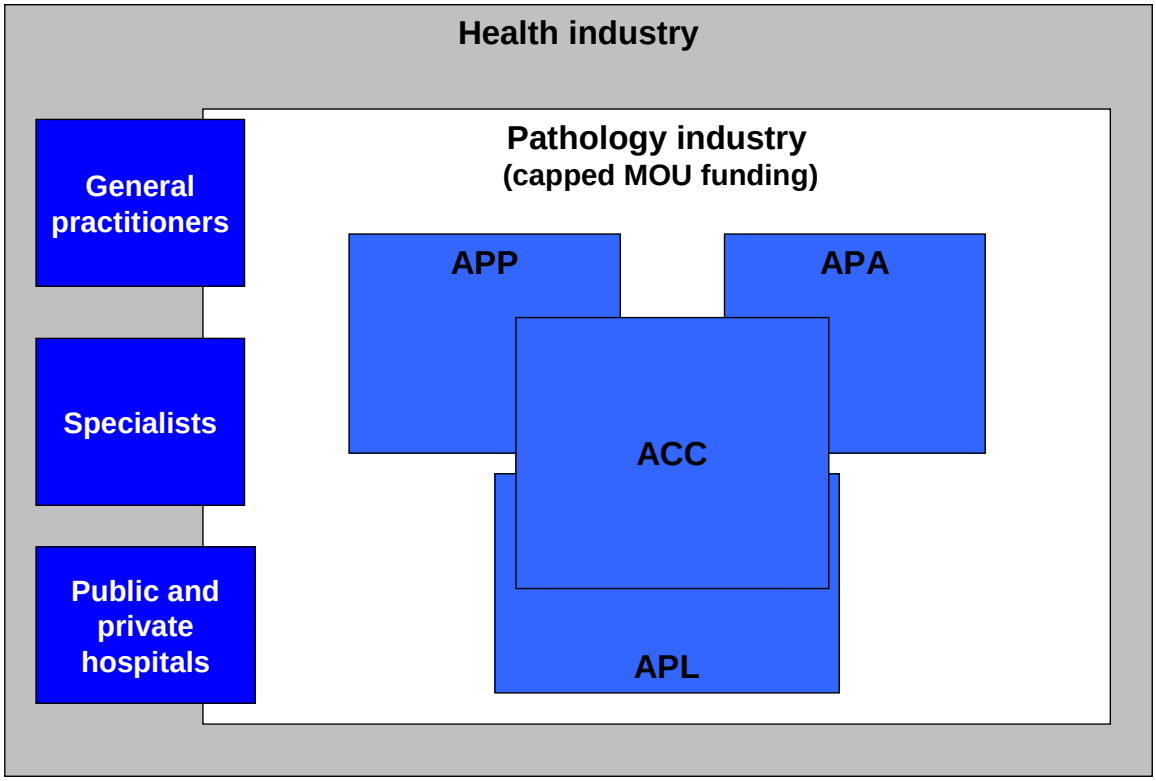
During this period of industry change, the number of pathology test services (excluding the patient episode initiation fee and referral fee), has increased from around 47 million in 2001-02 to around 55 million in 2004-05, an increase of around 16 per cent over the period. Future growth rates are expected to follow a similar trend.

Regulatory arrangements

Current approach to regulating ACCs

The following diagram illustrates the intricate relationships both within the pathology sector and between the pathology industry and other areas of the health sector. The ACC scheme is just one element of the regulatory arrangements, which impose conditions above and beyond the ACC requirements in order for providers to perform pathology services.

Figure 2: Key players in the pathology testing process



Given that a major aim of the NCP legislative review process is to reduce duplication and overlap in regulation in order to avoid unnecessary compliance costs and restrictions to competition, an assessment of the current regulation of ACCs needs to consider whether the regulatory arrangements for APAs, APPs and APLs are already meeting the objectives of regulating ACCs. The key regulatory requirements governing the profession is illustrated in the table below.

Table 1: matrix of regulatory requirements

Regulatory requirements	APA	APP	APL	ACC
Licensing	✓	✓		✓
Accreditation			✓	✓
Professional qualifications	✓	✓	✓	✓
Restrictions on number				✓
Fee/tax	✓	✓	✓	✓

Competitive restrictions

KPMG conducted a preliminary review of all competitive restrictions in the legislation governing the pathology industry, and identified the following restrictions for further investigation:

- ss.4A and 16(A)(5AA) and 23DNBA(2) of the *Health Insurance Act 1973;*
- cl.5(1), 5(2), 11(2), 11(3), 12(2), 12(4), 13, 15 and 16 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005*; and
- the Guidelines for Approved Pathology Collection Centres.

Key findings

Objectives of regulating ACCs

After careful consideration of historical information, discussions with stakeholders and the Department, KPMG considers that, to some extent, pathology market intervention could be justified in terms of:

- Access to pathology collection services – providing access to pathology collection services is essential to ensuring high quality health outcomes for society.
- Protection of consumers and human health – without sufficient quality controls on collection centre the risk of errors in the overall testing process will be greater. This has implications for consumers and human health.
- Allocation of public resources – the pathology industry operates under a funding Memorandum of Understanding with the Australian Government, which provides for target annual growth rates of between 4.6 per cent and 5.8 per cent over the life of the agreement (2004-09). Given that the pathology testing is predominantly funded by the public purse, the Government has an interest in ensuring that funding is allocated in an efficient and effective manner.

These broadly translate to the following objectives:

- Timely patient access to quality pathology services;
- A sustainable, competitive, and efficient industry; and
- Contribute to the management of outlays under a capped agreement.

While stakeholders emphasised that ‘cost reduction’ should be an explicit objective of regulation KPMG does not consider, given the objectives of NCP, this is a sufficient rationale for regulation. Hence cost reduction is not an appropriate objective of regulating ACCs.

Appropriate form of regulation

Given the objectives outlined above and in light of the industry structure, KPMG considered a range of alternative forms of regulation. These included:

- Positive licensing (status quo);
- Self regulation;
- Co-regulation;
- Certification; and
- Negative licensing.

Despite the presence of a strong industry association with relatively broad coverage, there is a clear polarisation of views between large providers and small to medium providers. For this reason KPMG does not consider self-regulation or co-regulation to be viable options at this point in time.

Negative licensing was also not considered an appropriate regulatory option. It effectively screens-out poor quality suppliers 'after the fact" and is therefore not considered appropriate where objectives relate to the protection of human health and safety.

Licensing or accreditation were deemed to be appropriate options for regulating ACCs.

Operational restrictions

A range of operational restrictions contained within the broader licensing framework were identified. These specifically related to:

- eligibility to apply for a licence to operate a collection centre;
- standards of operation, equipment and personnel;
- the number of collection centres; and
- prices.

Restrictions on eligibility to apply for a licence to operate a collection centre

Clause 5 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* places explicit restrictions on who can apply to operate a collection centre. The problems with the restrictions on eligibility, from a competition perspective, is that they:

- prohibit certain market participants from operating collection centres (eg, Category B & M laboratories); and

- create different rules for market participants depending on the time at which they were in operation (eg, Category S laboratories).

Restrictions on standards of operation

Clause 4 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* requires an application for an eligible collection centre to have on premises the necessary equipment and appropriate staff for the collection and preparation of specimens for pathology procedures.

The NPAAC *Standards for Pathology Laboratories* explicitly state that the "collection of specimens should be performed in appropriate facilities and under appropriate conditions" while the NPAAC *Guidelines for Approved Pathology Collection Centres 2006* lists the minimum requirements to apply to collection centres. Laboratories are also required to apply for NATA accreditation to be eligible for Medicare benefits.

Although a number of stakeholders emphasised that the current system of collection centre accreditation was working well in ensuring quality of specimen collection, it was revealed during consultation that, as part of the laboratory assessment process, NATA performs few inspections of ACCs. It was also revealed that in practice, this is usually limited to the collection centre attached to the laboratory. Hence, unlike laboratories, not all collection centres are inspected or accredited.

Given that collection centres in rural and regional areas are generally some of the furthest away from the laboratories, and hence less likely to be inspected, some stakeholders were concerned about quality in these centres. Further, these centres often have lower throughput than their metropolitan counterparts, and are therefore likely to be less profitable and hence face greater cost pressures. Without sufficient quality controls, there may possibly be a risk that a firm subject to price regulation will reduce quality in its endeavours to maximise profits. Some stakeholders confirmed these concerns with comments such as "there are collection centres out there that do not meet the standards".

Comments of this nature are concerning because any potential fall in the quality of collection centres has the potential to impact on the quality of the overall testing and reporting process, and hence the health outcomes for the consumer and the economy more broadly. Importantly, lower quality health outcomes lead to increases in the costs of health service over the medium to longer term.

Restrictions on the number of collection centres for new entrants

The *Health Insurance (Eligible Collection Centres) Approval Principles 2005* places restrictions on the number of collection centres an APA can operate. There are essentially two, somewhat interrelated, components of these arrangements that require investigation. These include:

- the licence cap (through the use of an allocation mechanism); and

- the quota system (including the use of a 'floor').

Licence allocation method

The allocation factor (i.e. the patient episode benchmark) to earn a unit of entitlement is currently set at 14,200. This represents the ratio of MBS episode activity to allocated units of entitlement as at July 2001 and was calculated from MBS and Department of Veteran Affairs (DVA) episodes performed over the period 1 January 2000 to 31 December 2000 by date of service.

Many industry stakeholders expressed concerns that the current ACC scheme imposed asymmetrical limits to growth across pathology providers, enabling large players to benefit from organic industry growth but precluding the smaller players from sharing in this growth.

KPMG reviewed the current use of the patient episode benchmark and has identified some inherent problems with the current approach. In particular:

- the number is static rather than dynamic and does not reflect the evolving nature of the market and the profession;
- the number is backward looking. That is the information underpinning the calculated unit of entitlement was based on activity data from 1 January 2000 to 31 December 2000;
- it is not an accurate reflection of the average throughput of a collection centre. Preliminary estimates indicated that the average throughput of a collection centre is in the vicinity of 6,000 patient episodes per year; and
- it inhibits the growth of smaller providers while facilitating the growth of larger providers, hence it creates an uneven playing field.

Licence floor

The *Health Insurance (Eligible Collection Centres) Approval Principles* provides for a temporary floor of two entitlements for the first two years of operation. After this period entitlements are based on the '14,200' rule.

During consultation small and medium providers continually emphasised that these provisions are a significant barrier to entry for new entrants because:

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

Collection centres in rural and remote areas

Clause 10 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* permits the holder of a unit of entitlement in certain specified rural and remote areas to cover three licences.

While the objective of this provision is clearly to enhance access to pathology collection services in rural and remote areas, there appears to be significant confusion regarding the operation of the scheme. More specifically, this relates to which regional classification system is employed to determine eligibility to operate ACCs under the provision.

While some stakeholders believed that the current system is an effective means of providing access to pathology collection centres in rural and remote areas, other stakeholders believed that access remained a key issue for the current licensing arrangements. Of concern are the reports that the 3:1 provisions are being used in what are now generally considered Outer Metropolitan Areas.

At a high level, the current rural / remote scheme appears to successfully encourage pathology service providers into remaining in those areas classified as rural or remote. We consider the main concerns with this scheme relate to the outdated classification system rather than its overarching concept. Given the population profiles of Australian regions have undoubtedly changed since the 1991 census, the rural / remote incentives for the pathology industry should match in context the outcomes of the RRMA review. However this will require a structured concordance process to educate stakeholders of changes in classifications.

Restrictions on price

Section 4A of the *Health Insurance Act 1973* states:

> (1) The regulations may prescribe a table of pathology services table that sets out the following:
>
> (a) items of pathology services;
>
> (b) the amount of fees applicable in respect of each item;
>
> (c) rules for interpretation of the table.

The table, including lists of the items of pathology services and the amount of fees applicable for each item is set out in the *Health Insurance (Pathology Services Table) Regulations 2005.*

For providers that choose to bulk bill, the Medicare rebate is their sole source of funding (because patients do not incur any out of pocket expenses). However, providers that do not bulk bill have two choices: they can privately bill the patient at a level that includes a gap payment (the difference between the Medicare rebate and the charge for the episode) or accept the Medicare rebate as payment. The decision of whether to bill or accept the Medicare rebate is essentially an organisational decision and to some extent a competitive market decision.

It is important to note that these provision do not restrict providers from providing different services (eg, non-Medicare funded pathology tests) or charging more than the Medicare rebate for providing the tests.

Licence taxes

Under section 23DNBA(2) of the *HIA* an approval for an eligible collection centre will not be granted until the tax on the grant has been paid.[1] The tax, is currently set at $1,000 per annum (pro rata for part thereof) and paid to Medicare Australia at the time of application.

In addition to the ACC licence tax there are a range of fees levied on the pathology industry. In addition to the licensing tax/fee there are costs associated with Quality Assurance (proficiency testing) and NATA inspection of laboratories which will vary depending on the range of testing and the size of the laboratory.

A few stakeholders considered that the licence fee structure was inappropriate and excessive and created barriers to entry, particularly for small providers and general practitioners.

An efficient licensing fee structure should be levied on a cost reflective basis. That is, license fees should be set to cover the cost of administration and enforcement. As such, both the roles of the Medicare Australia, which is responsible for the administration of the ACC scheme,[2] and the Department of Health and Ageing, which is responsible for advising on the policy aspects of the scheme, should be considered in any cost analysis.

Based on the fee amounts and number of licences held KPMG has estimates that the licence fees/tax paid by the pathology profession in 2005 to the federal government was just under $3.5 million, of which nearly $2,000,000 was in the form of a tax (which is paid directly into consolidated revenue).

Restrictions on licence trading

During the course of the review discussions with stakeholders revealed that the trading of licences was occurring. While a clear majority of stakeholders emphasised that this **was not the intention** of the scheme, there are currently no regulatory provisions that restrict the trade in licences.

It is important to note that one of the key advantages of licence trading is that, with restrictions on access limited, trading allows those providers who value the licence the most to access it. Any prohibition on trading is in fact a restriction to competition and, in light of this NCP review, must be clearly justified in terms of its objectives.

Reform options and recommendations

Over the course of the review, it became increasingly clear that the method for allocating licence entitlements (including the justification for any allocation method at all) was a major and contentious issue facing the industry. It has historically been the subject of significant debate and careful consideration of the future mechanism is needed.

[1] Tax on the grant of an approval is imposed by the *Health Insurance (Approved Pathology Specimen Collection Centres) Tax Act 2000*.
[2] The administration role of the HIC includes the application of the principles of determination, allocation of units of entitlement, issuing of licenses and collection of license fees, and the detection of inappropriate practice and fraud in relation to collection centres and their operations.

However, KPMG considers there is clear justification for regulations surrounding eligibility to operate ACCs (e.g. APA status), quality standards and some form of rural / remote access provisions. Therefore we considered a range of allocation options in isolation of these factors. These included:

- Option One – no allocation of licences;
- Option Two – current allocation method;
- Option Three – allocation based on growth in all patient episodes;
- Option Four – allocation based on average throughput of ACC applied to ACC patient episodes only;
- Option Five – allocation based on average ACC throughput applied to all patient episodes; and
- Option Six – allocation based on average throughput of ACC on recognised regional basis.

To assess these options KPMG adopted a balanced scorecard approach which qualitatively scores each option against a range of criteria, being efficiency, equity, access, cost effectiveness and competition.

On this basis, Option One emerges with the highest score and is thus the preferred option. Accordingly, KPMG recommends that future regulatory arrangements for ACCs be based on the following:

- a licensing regime with eligibility based on:
  - status as an APA; and
  - meeting appropriate quality standards; and
- no restrictions on licence numbers.

1 Introduction

1.1 Background

As part of the Australian Government's commitments under National Competition Policy (NCP) KPMG was engaged to conduct an NCP review of the Approved (Pathology) Collection Centre (ACC) Arrangements.

The review, which was conducted under the direction and guidance of the Pathology Section of the Department of Health and Ageing (the 'Department'), follows the principles laid down in sub-clause 5(1) of the intergovernmental *Competition Principles Agreement (CPA)* which states that legislation or regulation should not restrict competition unless it can be demonstrated that:

- the benefits of the restriction to the community as a whole outweigh the costs; and
- the objectives of the legislation can only be achieved by restricting competition.

This review has been conducted in line with the Terms of Reference which are included at Appendix A.

1.2 Scope of the review

This Review considers the current arrangements for regulation of approved pathology collection centres. The legislative instruments reviewed were:

- *Health Insurance Act 1973 (HIA)*;
- *Health Insurance (Eligible Collection Centres) Approval Principles 2005*; and
- *Pathology Quality and Outlays Memorandum of Understanding (MOU)*.

1.3 Approach

KPMG conducted the review in close collaboration with the Department and the profession. Our approach involved the use of a number complementary methodologies, including the following:

- Desk research and analysis – this involved reviewing historical information (including internal Departmental documents, background papers, previous reviews, etc) and data. During the research and analysis process, KPMG worked very closely with the Department and the profession to extract accurate and comparable data.
- A Discussion Paper - upon commencement, KPMG prepared a brief Discussion Paper that set out the background to the evaluation, identified key issues and questions to be answered as part of the review process. This Discussion Paper was circulated to stakeholders on 1 May 2006.

- Stakeholder interviews – as part of the review process KPMG conducted numerous one-on-one interviews, group discussions and telephone interviews with stakeholders. Consultation was held with representatives from the following:
  - small, medium and large providers;
  - public and private providers;
  - corporate and not-for profit providers;
  - niche providers; and
  - general practitioners.
- KPMG also presented at the Australian Association of Pathology Providers (AAPP) Member council meeting in Canberra on 25 May 2006.
- Formal submissions – KPMG received a small number of formal submissions to the review, some of which are commercial in confidence.

All stakeholders wishing to comment on the review were provided with the opportunity to do so.

1.4 Report structure

The remainder of this report is structured into the following chapters:

- Chapter Two provides an overview of the Government's Competition Policy Reform Agenda including National Competition Policy requirements as well as the Council of Australian Government's (COAG's) future reform agenda.
- Chapter Three profiles the operation of the Australian pathology industry and investigates key trends over time.
- Chapter Four describes the current regulatory arrangements governing the Australian pathology profession.
- Chapter Five considers the objectives of regulating ACCs.
- Chapter Six considers alternative options for regulating ACCs.
- Chapter Seven analyses the competitive restrictions currently contained in the legislation.
- Chapter Eight assesses alternative options for regulating collection centres.

- Chapter Nine summarises the key findings and the recommended option for future regulation of collection centres. It also provides details on a process for implementing any future changes to the regulatory framework.

- Chapter Ten provides a brief discussion of some issues raised during the course of the review but deemed to be outside of the Terms of Reference.

1.5 Disclaimer

1.5.1 Inherent Limitations

This report has been prepared as outlined in Section 1.3 of this report. The procedures outlined in Section 1.3 constitute neither an audit nor a comprehensive review of operations.

No warranty of completeness, accuracy or reliability is given in relation to the statements and representations made by, and the information and documentation provided by the Department of Health and Ageing, and those consulted as part of the process. KPMG has indicated within this report the sources of the information provided. We have not sought to independently verify those sources unless otherwise noted within the report. KPMG is under no obligation in any circumstances to update this report, in either oral or written form, for events occurring after the report has been issued in final form. The findings in this report have been formed on the above basis.

1.5.2 Third Party Reliance

This report is solely for the purpose set out in Section 1.3 of this report and for the Department of Health and Ageing's information, and is not to be used for any other purpose or distributed to any other party without KPMG's prior written consent.

This report has been prepared at the request of the Department of Health and Ageing in accordance with the terms of KPMG's contract dated November 2005. Other than our responsibility to the Department of Health and Ageing, neither KPMG nor any member or employee of KPMG undertakes responsibility arising in any way from reliance placed by a third party on this report. Any reliance placed is that party's sole responsibility.

2 The Government's Competition Policy Reform Agenda

2.1 National Competition Policy

In April 1995, the Commonwealth, States and Territories agreed to implement National Competition Policy (NCP) reforms. As a result, all governments signed the inter-governmental *Competition Principles Agreement (CPA)*, providing a commitment to ensuring that new and existing legislation does not impose undue restrictions on competition:

> "The guiding principle is that legislation (including Acts, enactments, Ordinances or regulations) should not restrict competition unless it can be demonstrated that:
>
> a) the benefits of the restriction to the community as a whole outweigh the costs; and
>
> b) the objectives of the legislation can only be achieved by restricting competition."
>
> Competition Principles Agreement, sub-cl.5(1).

The aim of the sub–cl.5(1) test, generally known as 'the competition test' is to establish whether particular restrictions on competition remain necessary, through an assessment of the costs and benefits of current and alternative means of achieving policy objectives. The burden of proof is on governments to establish a public interest case for the retention or enactment of legislation that has the effect of restricting competition.

Legislation can restrict competition in a number of ways. That is, legislation may restrict competition if it:

- establishes an outright prohibition of business activity;
- establishes or protects a monopoly;
- provides for the licensing or registration of participants in a business activity;
- allocates quotas/franchises;
- requires specific quality/technical standards for specific equipment;
- establishes price controls (including direct and indirect controls);
- nominates preferred customers or suppliers;
- confers differential benefits on particular persons/entities;
- provides for natural resource access licensing;
- establishes participation limits (on overseas/interstate participants);

- establishes barriers to entry or exit (often through licensing/registration);
- imposes restrictions on business structure, form or ownership;
- imposes restrictions on business conduct;
- imposes potential impediments to innovation (eg, through quality standards);
- promotes inefficient cross–subsidies between classes of goods and services; and/or
- promotes efficiency losses through excess regulation.

NCP acknowledges that competition is not an end in itself. That is, although competition will generally benefit the consumer, there will be instances where community benefit will be greater by not introducing the specific reforms or by introducing alternative reforms. Hence, competition is to be introduced to the extent that the benefits to be realised from competition outweigh the costs – that is, there is a net public benefit.

Sub-clause 1(3) of the *CPA* provides for considerations other than strictly economic criteria in assessing public benefit. These include:

(a) Government legislation and policies relating to ecologically sustainable development;

(b) Social welfare and equity considerations, including community service obligations;

(c) Government legislation and policies relating to matters such as occupational health and safety, industrial relations, access and equity;

(d) Economic and regional development, including employment and investment growth;

(e) The interests of consumers generally or of a class of consumers;

(f) The competitiveness of Australian businesses; and

(g) The efficient allocation of resources.

This is called the 'public interest' test. It is important to recognise that the 'public interest test' is not an exhaustive test, but rather provides a list of factors that should be considered when investigating the impacts of particular restrictions to competition.

If, on balance, the costs of restrictions to competition outweigh the benefits, then the restriction should not be retained. Even if, on balance, there are net benefits arising from restrictions, the legislation should only be retained in its current form if its objectives cannot be achieved more efficiently through other means, including non-legislative approaches.

2.2 Council of Australian Government's reform agenda

On the 10th of February 2006 the Council of Australian Governments (COAG) held its 17th meeting to discuss a range of issues of national significance. A major outcome of the meeting was the establishment of a new National Reform Agenda proposing reforms in two broad areas. The first focused on efforts to increase the competitiveness of Australian businesses through reforms to regulation and infrastructure. The second centred on measures to build the capabilities of people through reforms in health, education and training, and work incentives.

While COAG recognises that effective regulation is essential to ensure markets operate efficiently and fairly, to protect consumers and the environment and to enforce corporate governance standards, it was emphasised that the benefits from regulation must not be offset by unduly high compliance and implementation costs.

COAG agreed to a range of measures to ensure best-practice regulation making and review. In particular it was agreed that all governments will:

- establish and maintain effective arrangements to maximise the efficiency of new and amended regulation and avoid unnecessary compliance costs and restrictions on competition;

- undertake targeted public annual reviews of existing regulation to identify priority areas where regulatory reform would provide significant net benefits to business and the community;

- identify further reforms that enhance regulatory consistency across jurisdictions or reduce duplication and overlap in regulation and in the role and operation of regulatory bodies; and

- in-principle, aim to adopt a common framework for benchmarking, measuring and reporting on the regulatory burden.[3]

[3] Council of Australian Government, *Communiqué of the Council of Australian Governments 17th Meeting*, 10 February 2006.

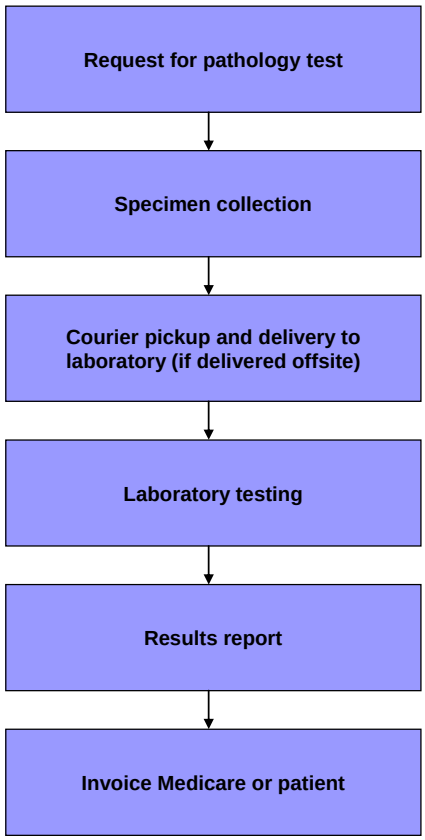
3 Pathology industry

This section provides an overview of the Australian pathology industry and the various entities involved.

3.1 Overview

The following diagram illustrates the process for a general pathology test, from referral to invoicing.

Figure 3: The process for a general pathology test



Source: Symbion Health Ltd, Pathology environment presentation, 2005[4] and KPMG.

There are a range of pathology service types. These cover areas such as anatomical pathology (histology), chemical pathology, genetics, haematology, immunopathology, microbiology and general pathology.[5] Depending on these service types, there are a number of locations where a specimen may be collected including the patient's residence, a medical practice, a hospital, a nursing home, or at a collection centre. Not all tests can be collected at any location, for

[4] Csoban, P., Symbion Health Ltd: Pathology environment presentation, 2005. Accessed at http://www.symbionhealth.com/files/292125.pdf on 11 May 2006.
[5] As described by the RCPA at http://www.rcpa.edu.au/public/pathology/discipline.cfm accessed on 30 May 2006.

example, anatomical pathology specimens are generally removed during an operation at a hospital or a medical practice and these tests do not require specimen collection centres.

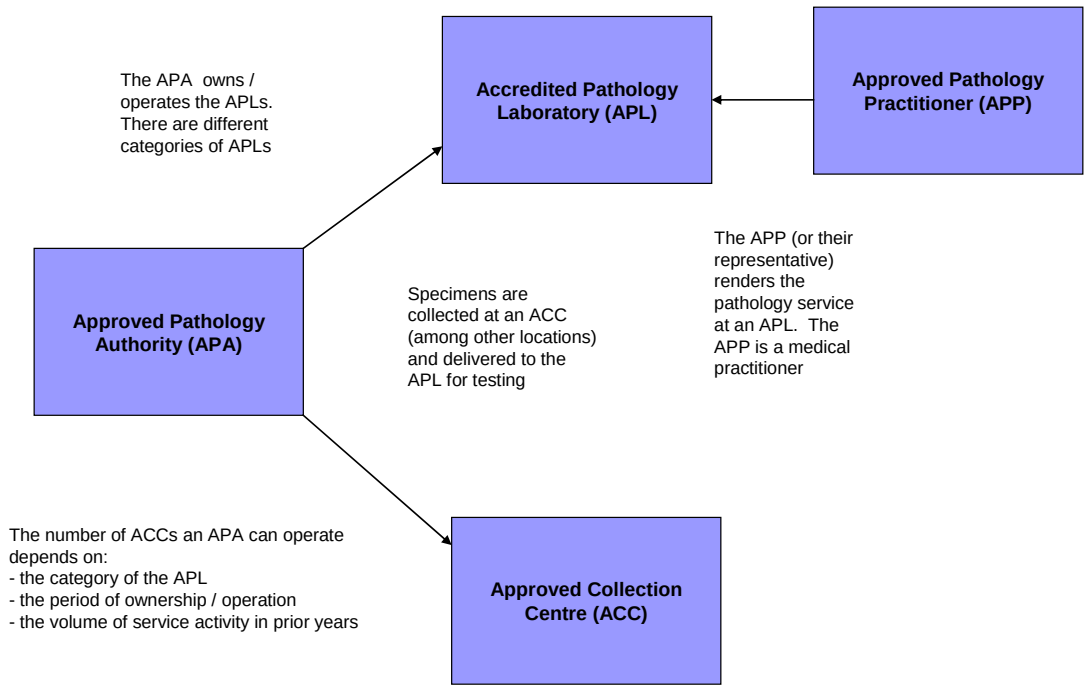
3.1.1 Key entities

Across these various service types there generally four types of entities:

- Approved Pathology Authorities (APAs) – the entities authorised to own/operate pathology laboratories and collection centres;
- Approved Pathology Practitioners (APPs) – the medical practitioner authorised to perform pathology tests;
- Accredited Pathology Laboratories (APLs) – the premises at which pathology tests must be performed; and
- Approved Collection Centres (ACCs) – one of the locations at which a pathology specimen for testing may be collected.

The relationship between these entities is illustrated in the following diagram.

Figure 4: Key entities involved in the pathology testing process



Source: KPMG.

3.1.2 Industry structure

The Australian pathology industry has undergone significant structural change over the past two decades, and is now dominated by a number of large corporatised entities. In addition to consolidation, there is a growing trend towards vertical integration of pathology providers with large medical practices containing significant number of general practitioners and hence a large referral base, sometimes with radiology and pharmacy practices – a 'one stop shop'.

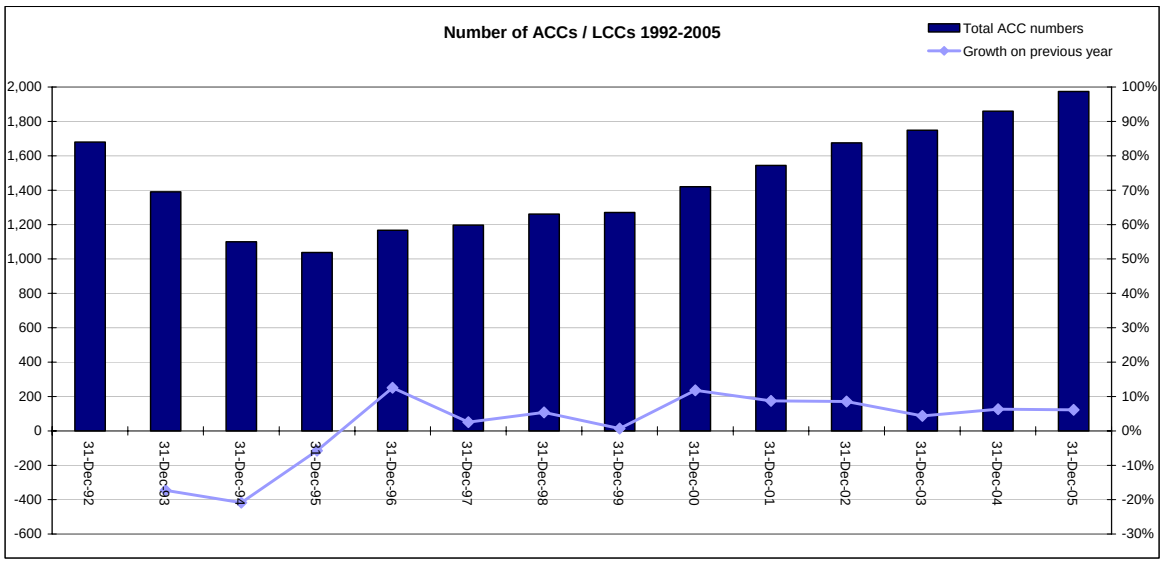
KPMG has obtained commercial in confidence data from the Department and publicly available data from the Medicare Australia website. Given that the data is collated from application forms and thus subject to human error, variability in interpretation or different approaches for completion, KPMG recognises that there are data limitations. In order to best represent the industry KPMG and the Department has sought independent advice on our analysis of the data.

This independent analysis has revealed that, while the data may not be faultless, the picture of the industry presented in this section is considered to be reflective of the developments in recent years and is reasonable in light of the nature of the information available to us.

3.1.3 Industry growth

Figure 5 illustrates the growth in the number of collection centres since the inception of the licensing scheme in 1992.

Figure 5: Number of collection centres, 1992 to 2005



Source: Department of Health and Ageing

As shown above, growth in the number of collection centres was volatile between 1992 and 2000, corresponding closely with the period of the first collection centre licensing scheme – the Licensed Collection Centre (LCC) scheme – that is, 1992 to 2001. From the commencement of the Approved Collection Centre (ACC) scheme in 2001, annual growth rates in collection centres slowed to between 4 and 9 per cent.

3.1.4 Market concentration

The Australian Competition and Consumer Commission (ACCC) is responsible for enforcing section 50 of the *Trade Practices Act 1974 (TPA)*, which

> 'prohibits acquisitions that would have the effect, or be likely to have the effect, of substantially lessening competition in a substantial market in Australia, in a state, territory or region of Australia.'

One of the factors the Australian Competition and Consumer Commission (ACCC) considers when evaluating whether a merger is likely to have the effect of substantially lessening competition is market concentration. That is, the number and relative size of players in the industry.

The ACCC has identified two key problems associated with a high level of market concentration. First, it can enable firms with large capacity to exercise unilateral market power. Second, it increases the scope for coordinated conduct amongst competitors[6]

Put simply, large firms in highly concentrated markets are generally able to exercise unilateral market power. All else being equal, in markets for standardised goods or services, the market shares of firms effectively correspond to their control of industry capacity. The larger the proportion of total capacity controlled by a firm, the less severely it must restrict its own output to extract price increases from consumers, and the more likely that this conduct will be profitable.[7]

Firms which exercise market power can also undertake 'strategic behaviour' such as predation, with a view to affecting market structure and power. For example, larger firms may be able to price below cost in the short-run with the specific objective of driving out smaller competitors. A reduction in the number of firms operating in a market consequentially increases the scope for coordinated conduct, including both overt and tacit collusion. Hence it becomes easier for firms to reach agreement on coordinated activities, signal their intentions and to monitor behaviour.

A high level of industry concentration also increases the scope for firms to coordinate their actions to collude overtly or tacitly. That is, the higher the level of concentration, the lower the number of firms, making it easier for firms to reach agreement on the coordination of activities (eg, positioning of businesses), signal their intentions to one another and monitor behaviour. In particular, where the large players have relatively even market shares, the commonality of their interest tends to be greater, strengthening their commitment to collusion. Once again, the result is higher prices for consumers; to the benefit of the industry but at a loss of overall efficiency.

The ACCC has identified that where market structure has been highly concentrated and market shares have been stable for a long period, this will tend to suggest that there are barriers to the entry of new market participants which might otherwise undermine and constrain the exercise of market power.

[6] Australian Competition and Consumer Commission, 1999, Merger Guidelines, AGPS, Canberra, p.43.
[7] ibid, p.44.

3.1.4.1 Measures of market concentration

The ACCC Merger Guidelines cites the four firm concentration ratio (CR4) as the measure of market concentration used to evaluate mergers in Australia. The CR4 is a measure of the sales of the four largest firms in an industry as a percentage of total industry sales.

The ACCC has developed generic industry concentration thresholds to evaluate merger proposals to determine whether they will have a significantly adverse impact on industry competition. These thresholds address concerns over the potential exercise of both unilateral and coordinated market power, with the ACCC giving further consideration to mergers if:

- the merger will result in a post-merger CR4 of 75 per cent or more and the merged firm will supply at least 15 per cent of the relevant market; or
- the merged firm will supply 40 per cent or more of the market. [8]

In a recent review of the thresholds the ACCC found that competition and efficiency issues arose in mergers which only just breached the thresholds. Given the ACCC' confidence in the threshold's ability to flag potential competition problems associated with specific level of industry concentration, KPMG proposes to use the CR4 to identify whether the current level of industry concentration has reached a level which may enable firms to exercise unilateral market power or lead to increasing coordination of activity.

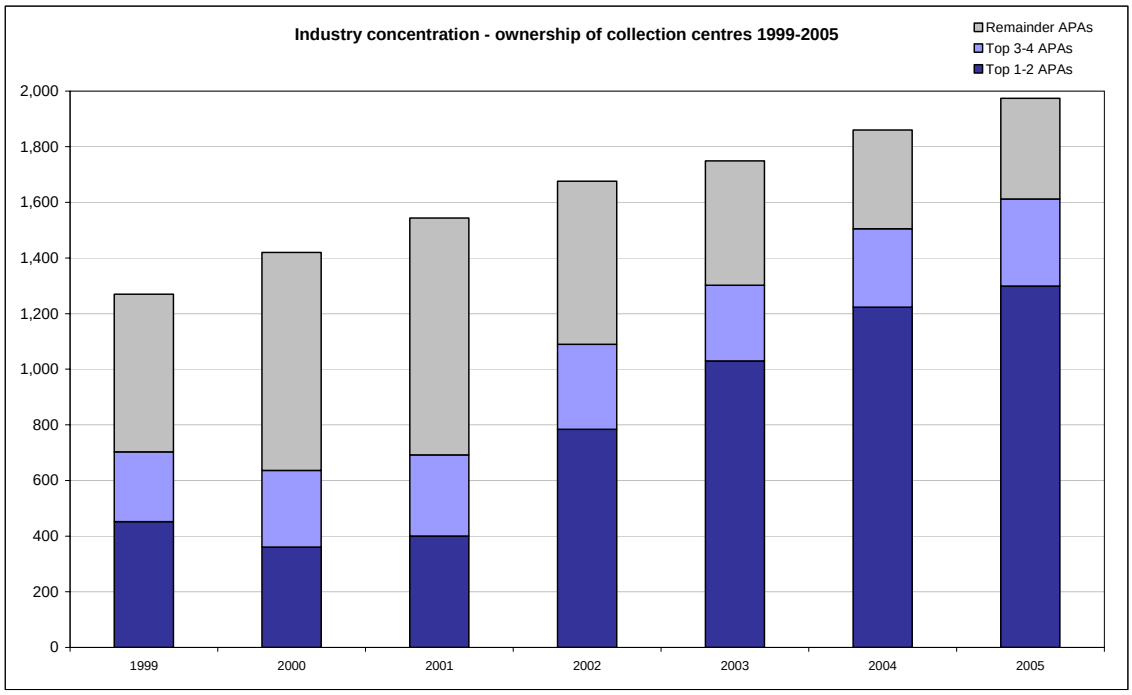
3.1.4.2 Actual market concentration

As shown in Figure 6 there has been a clear trend of increasing concentration of collection centre ownership over the period 1999 to 2005.

While the total number of collection centres has grown significantly over this period, it is interesting to note that the growth from 1999 to 2001 was predominantly driven by the growth in small providers. However from 2001 onwards the growth in collection centres has noticeably been driven by the large growth in collection centres held by the top two APAs.

[8] ibid, p.44.

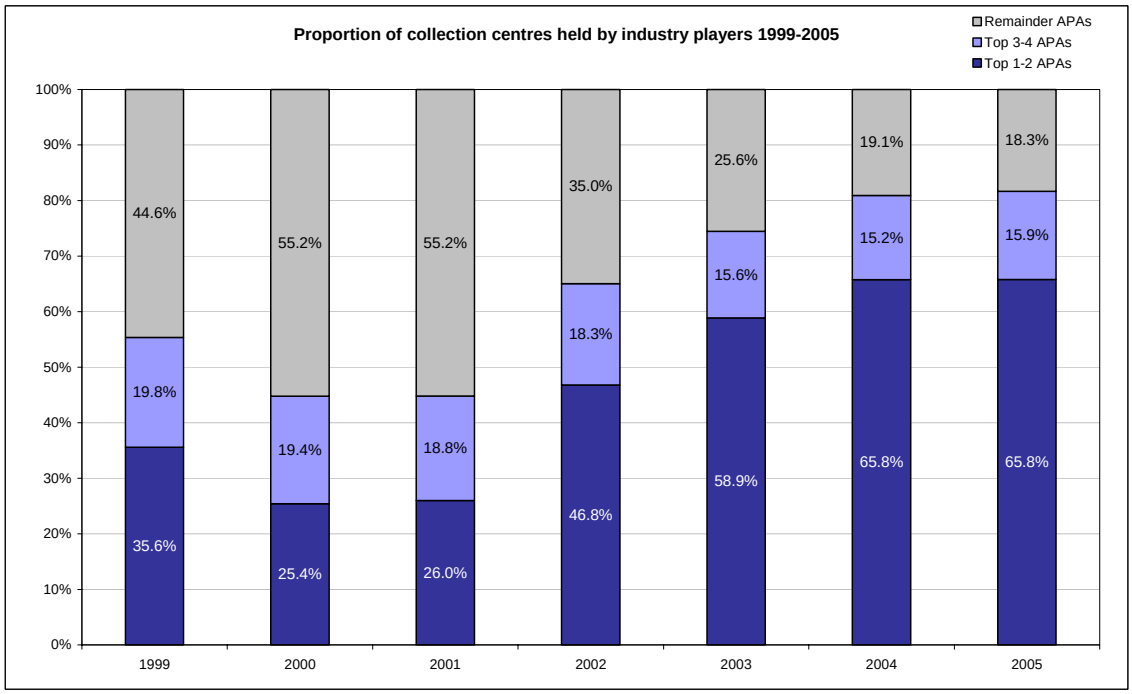
Figure 6: Ownership of collection centres, 1999 to 2005



Source: Department of Health and Ageing

Figure 7 illustrates the percentage of collection centres held by the top two APAs, third and fourth APAs, and the remaining APAs since 1999.

Figure 7: Proportion of collection centres held by industry participants, 1999 to 2005



Source: Department of Health and Ageing

As illustrated in the above table, since the introduction of the ACC scheme, the top four industry players have increased their share of collection centres from 44.8 per cent to 81.7 per cent. Furthermore the top two APAs account for 65.8 per cent of collection centres, which has increased from 26.0 per cent since the ACC scheme's commencement. Conversely, small providers have seen their share of collection centres fall, from 55.2 per cent to 18.3 per cent.

Based on the above information KPMG notes that:

- the top four industry players hold a market share exceeding the 75 per cent threshold identified by the ACCC (81.7 per cent); and
- the top two industry players hold market shares of 35.7 per cent and 30.1 per cent respectively, well above the 15 per cent threshold identified by the ACCC.

3.1.4.3 Implications for the review

The ACCC notes that a concentrated market is a necessary but not sufficient condition to enable the exercise of market power.[9] That is, market concentration is one of many factors monitored by the ACCC when examining potential mergers for impacts on competition. Other factors considered by the ACCC include:

- the actual and potential level of import competition in the market;
- the height of barriers to entry;
- the degree of countervailing power in the market; the likelihood that the acquisition would result in the acquirer being able to significantly and sustainably increase prices or profit margins;
- the extent to which substitutes are available in the market, or are likely to be available in the market;
- the dynamic characteristics of the market, including growth, innovation and product differentiation;
- the likelihood that the acquisition would result in the removal from the market of a vigorous and effective competitor; and
- the nature of vertical integration in the market.[10]

Hence, the effect on competition of relatively high levels of market concentration may differ between markets and will need to be considered on a case-by-case basis.

[9] For example, if the relevant market is properly defined, a firm or firms will not normally be able to exercise market power in the absence of a significant market share.
[10] Australian Competition and Consumer Commission, 1999, Merger Guidelines, AGPS, Canberra.

For example, while the retail grocery industry had similarly high levels of market concentration for year end 26/01/2003 (with Woolworths accounting for 42.0 of market share and Coles/Bio-Lo accounting for 35.2 per cent of market share), the ACCC, concluded that:[11]

> The [grocery retail] industry remains innovative and competitive, with new entry in the form of players such as Aldi and Pick 'n' Pay, which in the Commission's view are helping to maintain competitive tension in the markets in which they operate.
>
> The independent sector provides a competitive influence at both levels of the supply chain through individuals wholesalers and retailers and the emergence of retail banner groups.
>
> This is not to say that the ACCC is not conscious of the potential competition problems that continued acquisitions may result in and it will continue to assess acquisitions in the grocery industry in the context of the state of the market at that particular time.

The market for pathology collection centres on the other hand is quite different to that of the retail grocery sector. While both industries exhibit high levels of market concentration, the pathology industry also has high barriers to entry, low levels of countervailing market power, very little product differentiation and no import competition, factors likely to exacerbate the ability of larger firms to behave anti-competitively. Hence, the impact on future market concentration levels and the subsequent impact of competition needs to be given careful consideration in this review.

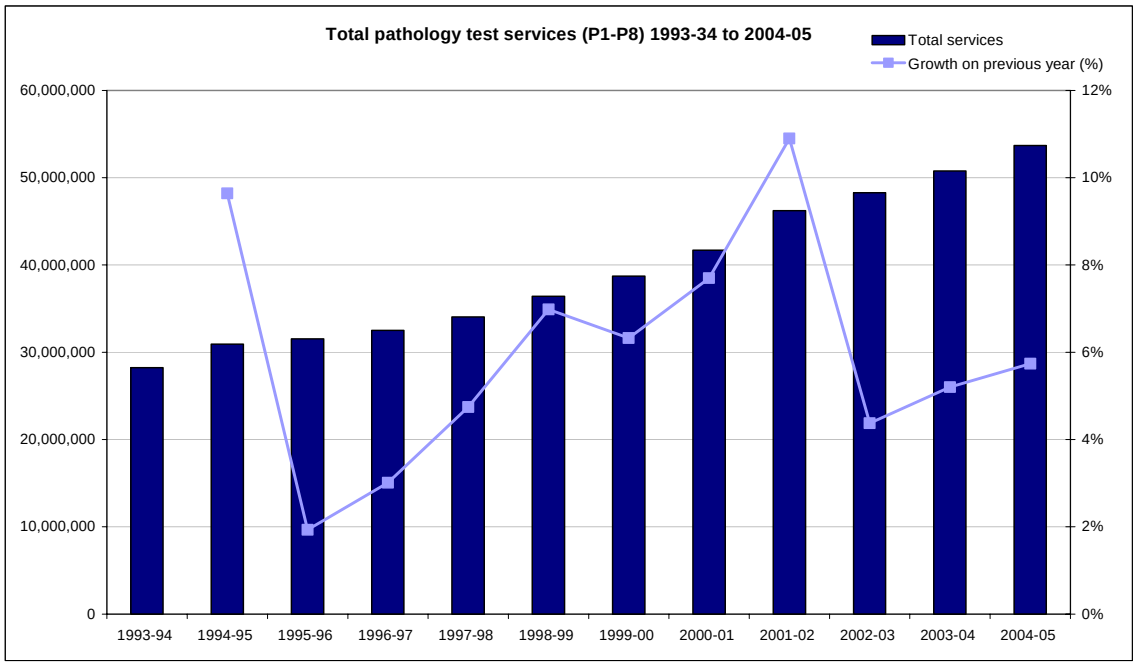
3.2 Demand for pathology services

Demand for pathology services is a derived demand, meaning that the majority of services are provided upon referral from a medical practitioner and therefore the volume of pathology services is also dependent on the community's demand for medical services.

That is, because the medical practitioner requests the pathology service, the final customer (i.e. the patient) does not directly drive demand on their own account. In fact, marketing efforts by pathology providers are directed to medical practitioners to secure referral streams, and in this sense, the medical practitioners are the 'customers' of the service. Furthermore, the reimbursement under Medicare for the majority of pathology services and high rate of bulk billing by pathology providers also means neither the medical practitioner nor the patient pays for the pathology services undertaken on their behalf.

[11] Australian Competition and Consumers Commission, 2004, *assessing shopper docket petrol discounts and acquisitions in the petrol and grocery sectors*, AGPS, Canberra.

Figure 8: Growth in pathology test services (P1-P8), 1993-94 to 2004-05



Source: Medicare Australia data.

As shown in Figure 8 the number of pathology test services (excluding the patient episode initiation fee and referral fee), which is a measure of demand, has increased from around 47 million in 2001-02 to around 55 million in 2004-05, an increase of around 16 per cent over the period. Future growth rates are expected to follow a similar trend, with demand for pathology services driven by:[12]

- requester induced demand – changes in:
  - medical practice – generational change in medical practitioners may result in more pathology being ordered (research indicates GPs below the age of 44 are more likely to order pathology tests than their older colleagues);[13]
  - preventive medicine – early diagnosis and intervention to prevent the development of more serious medical conditions potentially induces pathology referrals;
  - general practitioner (GP) corporatisation – GPs in a large corporatised medical centre may have different pathology ordering patterns than the traditional general practice;
  - litigation fears – GPs may order more pathology tests to avoid medical liability issues;
  - computerisation – the take-up of computers and pathology ordering software in general practice may make it easier for pathology (and more of it) to be ordered;

[12] AAPP submission to Productivity Commission, 2004, *Impact of advances in medical technology on healthcare expenditure in Australia*.
[13] Britt H, Knox S, Miller GC, Changes *in pathology ordering by general practitioners in Australia*, 1998–2001. AIHW Cat. No. GEP 13. Canberra: Australian Institute of Health and Welfare (General Practice Series No. 13).

- consultation length – longer consultations in general practice may result in more pathology tests being ordered with these consultations often terminated by the prescribing of medication or the ordering of tests;

- competition between GPs – a GP who orders more pathology might be seen as delivering a service of higher standard, especially to a patient who does not have a 'family' GP and 'shops around' for medical services;

- GP accreditation – more sophisticated accreditation and registrar training may prompt GPs to investigate more complex cases which might otherwise have been referred to a specialist, potentially resulting in more pathology being ordered; and

- demand by patients – more insistent and informed patients demand comprehensive analysis of their condition potentially involving greater diagnostic testing;

- government induced demand – changes in government policies such as private health insurance incentives, budget-funding initiatives, GP rebates, safety-net on Medicare gaps, and public health awareness programs, all of which may change the demand for secondary services such as pathology.

- external factors – changes in:

  - demographics – such as the ageing of the population will potentially lead to more pathology tests associated with geriatric conditions;

  - industry suppliers marketing activities – pathology providers may attempt to influence requesting practitioners' behaviour and ordering patterns; and

  - industry health promotions.[14]

  Essentially, demand for pathology services is driven by changes in medical practitioners' referral patterns, which in turn is influenced by a range of factors within the medical services industry and in the external environment. This emphasises the derived nature of demand for pathology services.

3.3 Summary

As illustrated, since the introduction of the ACC arrangements the number of collection centres has grown noticeably from 1,544 in 2001 to 1,974 in 2005. At the same time, the level of market concentration has increased significantly to levels above the ACCC thresholds deemed acceptable for competition to remain in post merger industry environments.

Given the current industry structure and the likely future growth in demand for pathology services, the regulatory arrangements need to provide an environment in which all players can compete equally, while meeting clearly specified objectives.

[14] The AAPP submission also cited provider induced demand, however we consider this refers to providers competing for market share rather than increasing overall demand for pathology services.

4 Regulation of the profession

This section describes the regulatory arrangements governing the Australian pathology industry, which the Australian Government administers through the Medicare Benefits Scheme (MBS).

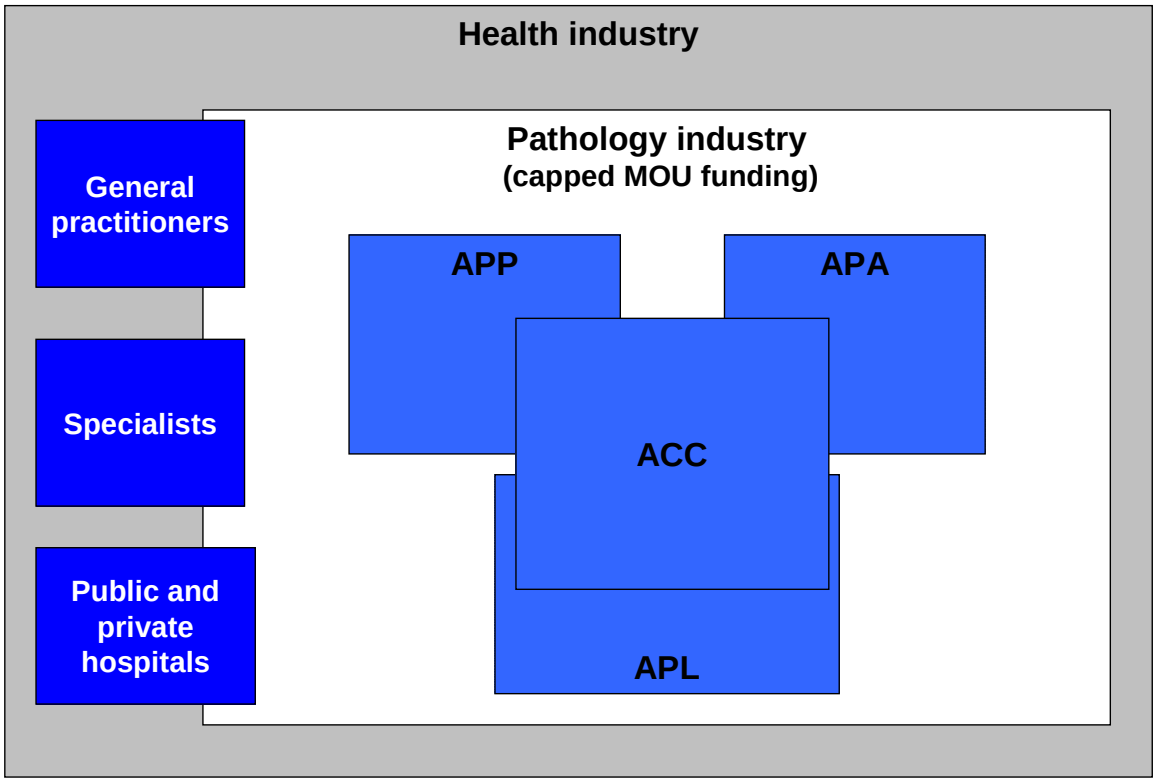
4.1 Regulatory arrangements

4.1.1 Overview

The pathology sector is complex with respect to both its internal governing regulations and its relationship with other health professions. While our terms of reference specifically relate to the competitive restrictions of the collection centre arrangements, it is important to recognise that they are but one component of the regulatory arrangements governing the Australian pathology profession. As such KPMG notes that it will be difficult, if not impossible, to assess these arrangements in pure isolation.

The following diagram illustrates the intricate relationships both within the pathology sector and between the pathology industry and other areas of the health sector, the ACC scheme is just one element of the regulatory arrangements, which impose conditions above and beyond the ACC requirements in order for providers to perform pathology services.

Figure 9: Key players in the pathology testing process



The diagram also illustrates that the industry is dependent on the general practice, specialist and hospital sectors for referrals, and thus developments in these sectors will impact on the pathology profession (i.e. the derived demand nature of pathology services).

4.1.2 Eligibility for Medicare funding

The *Health Insurance Act 1973 (HIA)* imposes conditions under which a pathology service will attract Medicare benefits. The overlying requirements for a Medicare benefit to be payable in respect of a pathology service are that it is:

- determined necessary by the treating practitioner;
- rendered by or on behalf of an approved pathology practitioner (i.e. APP);
- rendered in a pathology laboratory accredited for that kind of services (i.e. APL); and
- rendered in an APL owned by an approved pathology authority (i.e. APA); and
- collected either:
  - by the person themselves or at their place of residence;
  - by the treating practitioner or their employee;
  - at the premises of a recognised hospital, private hospital, nursing home or other institution, in which the person is a patient; or
  - at an approved collection centre which must be owned, leased or sub-leased by an APA that is also the sole proprietor of at least one APL.

These legislative provisions effectively establish a hierarchy of conditions that restrict the operation of an ACC and hence access to the MBS. That is, to operate a ACC, the applying entity must be an APA that also owns an APL, in which the test is to be undertaken by an APP. The following sections outline the legislative requirements to become / establish an APA, APP, APL and ACC.

4.1.3 Approved Pathology Practitioners and Approved Pathology Authorities

For a pathology test to be eligible for reimbursement under Medicare, it must be performed by an APP at a laboratory owned by an APA. The approval processes for APPs and APAs are similar, with both required to submit an undertaking to the Minister. An undertaking is essentially an agreement to act or refrain from acting according to specified protocols. The following table demonstrates the similarities between these undertakings.

Table 2: Categories of undertaking for APPs and APAs

Categories of undertaking	APP	APA
Comply with legislation	✓	✓
Ensure proper behaviour of person acting on their behalf (i.e. APP must supervise tests and APA must inform their representatives of undertaking)	✓	✓
Properly deal with persons (including themselves) who breach an undertaking or commit a relevant offence	✓	✓
Provide accurate information to Medicare Australia	✓	✓
Assure quality	✓	✓
Notify patients and practitioners of changes to those services they are approved to perform	✓	✓
Commit to not inducing requesting practitioners to use their services	✓	✓
Perform services only where APA and APP have in place an agreement / contract of employment	✓	✓
Inform Medicare of financial affair concerns		✓
Permit inspection of premises with 12 hours notice and cooperate with independent inspection body		✓
Notify Medicare of matters affecting approval of premises		✓
Hold only one APA approval per entity		✓

Source: Medicare Australia Applications for Approved Pathology Authority and Approved Pathology Practitioner.

There is an annual approval fee payable for both APPs and APAs, of $500 and $1,500 respectively.

Finally an APP must be a medical practitioner with their formal qualifications and experience explicitly considered by the Minister prior to approval as an APP.

4.1.4 Approved Pathology Laboratories

Medicare-eligible pathology tests must be performed in a laboratory accredited under the *Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002* ('the APL Principles').

The National Pathology Accreditation Advisory Council (NPAAC) establishes the required minimum laboratory standards for Medicare-eligible pathology services. The actual accreditation inspection is performed the National Association of Testing Authorities (NATA)

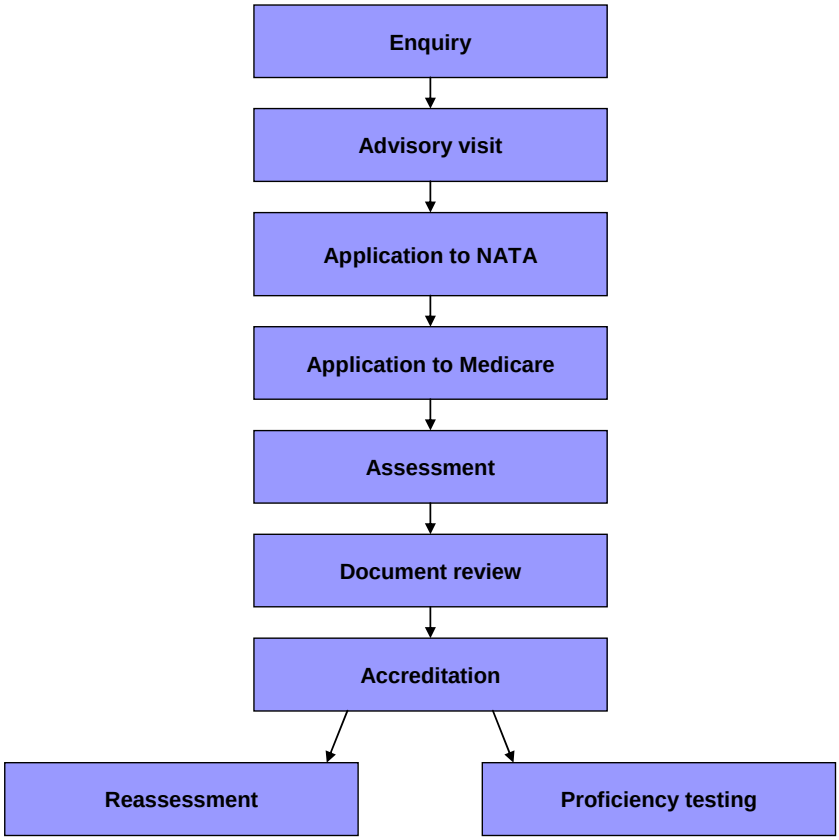
in conjunction with the Royal College of Pathologists of Australasia (RCPA). NATA is recognised by the Australian Government as the national authority for accreditation of laboratories.[15]

Individual laboratories apply to NATA for accreditation in one or more categories of medical testing, and then undergo an inspection by NATA-selected assessors. Once accredited, laboratories become members of NATA.

4.1.4.1 New laboratory accreditation

The application process for new laboratories seeking accreditation is outlined in the following diagram.

Figure 10: Application process for new laboratory accreditation



Source: About NATA and accreditation, 2004[16]

New applicants must arrange with NATA for an initial advisory visit, for which the laboratory must already have in place appropriate facilities, equipment and staff, as well as evidence of

[15] National Association of Testing Authorities, 2003, *Memorandum of Understanding between the Commonwealth of Australia and the National Association of Testing Authorities*, Australia..
[16] See: http://www.nata.asn.au/go/publications Accessed on: 13/06/2006.

quality assurance process (QAP) enrolment. These prerequisites are set out in the NATA Accreditation Requirements (NAR) for the relevant field of testing.

Following the advisory visit the laboratory must submit a formal application to NATA, following which the laboratory is issued a NATA / RCPA application number and report on the advisory visit. The laboratory may then lodge an application with Medicare for recognition as an APL, with which it must submit the advisory visit report. Once this is approved, the laboratory is able to process tests and claim the associated Medicare benefits.

The formal NATA assessment occurs approximately 3 to 4 months following the formal application to NATA, following which NATA provides an abbreviated assessment report for forwarding to Medicare. As a new laboratory is likely to have limited quality control and QAP data to review on the formal assessment, NATA may request year-end summaries and accreditation status may be reviewed in light of this information.[17]

4.1.4.2 Renewal of accreditation

Medicare requires APL approvals to be renewed every three years. NATA provides an abbreviated report especially designed for APL renewals which takes into account the laboratory's assessment history. These reports will only be issued for those laboratories that have complied with surveillance intervals and requirements for accreditation, providing the incentive for laboratories to avoid delays in periodic assessments.

Accredited laboratories are also encouraged to participate in proficiency testing activities as nominated by NATA to enhance their external quality assurance.[17]

4.1.4.3 Extension of accreditation

If a laboratory wishes to commence testing in areas outside its scope of accreditation, it must advise NATA, who will either perform a desktop review of QC and QAP data (for minor changes) or conduct additional on-site assessments (for significant extensions). The assessments are carried out prior to Medicare granting an extension to the existing accreditation.[17]

[17] NATA website Found at: http://www.nata.asn.au/index.cfm?objectId=AD74874A-933B-BBCB-A904EAE6169EF49A Accessed on 13/06/2006.

4.1.4.4 Fees for accreditation

The following table sets out NATA's fee schedule for medical laboratory accreditation.[18]

Table 3: Laboratory accreditation fee schedule

Accreditation service	Expense covered	Fee
NATA Accreditation Requirements (NAR)	Publication	$55 each
Advisory visit	Preparation, on-site visit, in-office activity and reporting time Travel, accommodation and associated expenses	$176 / hour At cost
Documentation review	Preparation, on-site visit, in-office activity and reporting time Travel, accommodation and associated expenses	$176 / hour At cost
Application fee		$900
Initial assessment and non-routine reassessments	Preparation, on-site visit, in-office activity and reporting time Travel, accommodation and associated expenses	$176 / hour At cost
Certificate of Accreditation	Additional certificates (first certificate is free)	$77 each
Annual membership	Cover cost of routine reassessments. Usually no additional time or travel costs are levied.	Depends on distance from capital city GPO 0-100km $2,070 100-200km $2,175 200-750km $2,280 750-1500km $2,380 Over 1500km $2,490

Source: NATA 2006-07 Fee Schedule

4.1.4.5 Laboratory standards

NPAAC establishes standards ranging from broad overarching standards to specific standards for laboratories undertaking particular pathology services. The broadest of the NPAAC standards is the NPAAC *Standards for Pathology Laboratories* which came into effect on 1 January 2003. These provide the minimum standards acceptable for good laboratory practice in

[18] NATA 2006-07 Fee Schedule. Found at: http://www.nata.asn.au/go/publications Accessed on: 13/06/2006.

Australia and apply to all pathology laboratories seeking accreditation. There are nine standards which relate to:

1. laboratory ethics;
2. quality systems;
3. staffing, supervision and consultation;
4. facilities;
5. pre-analytical phase;
6. analytical phase;
7. post-analytical phase;
8. health and safety; and
9. audit and assessment.

Other broad standards which are required for accreditation relate to *Quality Systems for Medical Laboratories* and *Requirements for Supervision of Pathology Laboratories.*

To be accredited, the laboratory premises must also meet relevant standards for the kinds of pathology services to be provided and specific requirements depending on the category of the laboratory. The laboratory categories (GX, GY, B, M and S) depend on the range of pathology tests performed and the presence of pathologists at the laboratory premises. The Laboratory Principles also specify standards of direction, control and supervision required at each laboratory category.

4.1.4.6 Review of laboratory accreditation

The current pathology laboratory accreditation arrangements were reviewed by Corrs Chambers Westgarth Lawyers, at the request of the Department of Health and Ageing (the Commonwealth pathology services review). The July 2002 report of the review found that present arrangements were fundamentally sound and should be maintained.

> [C]urrent Australian pathology laboratory accreditation arrangements efficiently and effectively regulate the vast majority of pathology services provided in Australia. There is substantial qualitative evidence that the quality of pathology services has improved since the present arrangements were introduced.[19]

KPMG notes that this review was conducted prior to the introduction of the revised NPAAC Standards for Pathology Laboratories, and as such the standards may have increased since this review.

[19] Corrs Chambers Westgarth, *Evaluation of the Australian Pathology Laboratory Accreditation Arrangements (2002), Department of Health and Ageing,* Canberra, 2002.

4.1.5 Pathology Collection Centres

Since the mid 1970s, there have been two consecutive and related arrangements regulating the collection centres for Medicare eligible pathology services. These were the LCC scheme and the ACC scheme respectively.

4.1.5.1 Licensed Collection Centre (LCC) scheme

The LCC scheme, introduced in 1992, set out to reduce the number of collection centres across Australia by setting a limit on the number of permanently licensed collection centres and phasing out the remainder by restricted temporary licences. The aims were to improve the efficiency of specimen collection centre services and ensure that the services were of a satisfactory standard. The LCC scheme was designed 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.

In 1992 the Government announced a fee reduction to contain growth in Medicare expenditure, and the LCC scheme was concurrently implemented to assist the industry reduce costs and better cope with the revenue cut. It was believed that if left unregulated, the closure of commercially unsustainable collection centres brought about by insufficient revenue would give competitors the opportunity to fill such vacancies and boost market share.

Accordingly the LCC scheme aimed to:

- reduce the number of collection centres by limiting the number of LCCs;
- increase the efficiency of pathology specimen collection;
- ensure that future growth of collection centres occurred in an orderly manner;
- ensure that all collection centres were of a reasonable standard; and
- allow flexibility to the industry to make decisions on whether to apply for units of entitlement and licences, and the number and location of collection centres.[20]

Under the LCC scheme, eligible private-sector APAs were allocated units of entitlement from a fixed pool which could be used to operate a collection centre on a one-for-one basis. The exception to this rule related to collection centres in rural and remote areas, in which one unit of entitlement could be converted to three collection centres.

The mechanism for allocating units of entitlement was based on a formula which was detailed in a determination under the Act. While there were essentially five determinations over the life of the scheme the formula for allocating units of entitlement generally:

- was based on a provider's 1991 market share (based on data reported by the APA), defined in terms of:

[20] Review of the LCC Scheme, Background information and issues for discussion, PCC 37, 1998.

- the average daily number of episodes of patient testing;
- number of full time equivalent (FTE) pathologists; and
- number of requesting practitioners;

- each APA received an additional licence for a collection centre situated at a each Category G laboratory the operate; and
- 'new entrants' into the market received an initial allocation of two units of entitlement, one of which had to be for a laboratory based collection centre.

Finally the LCC scheme required the collection centres to be operated by an APA on premises owned or leased by that same APA, as well as maintaining appropriate equipment and supplies for the collection of pathology specimens.

The LCC scheme was not flawless and several problems arose from its operation, including:[21]

- the formula did not necessarily give the best indicator of market share and could create industry instability by generating considerable changes in entitlements between APA's in the event of mergers and takeovers;
- to address potential industry instability, a 'floor arrangement' was established to guarantee no loss of entitlements. This arrangement contradicted one of the main objectives of the LCC scheme, being to maintain orderly growth in the number of collection centres;
- the LCC scheme excluded public sector APAs except for "grandfathered" centres; and
- the legislation and administration required for the LCC scheme was complex and time consuming for both the government and the pathology industry.

4.1.5.2 The ACC scheme

To address the flaws of the LCC scheme, pathology industry stakeholders and the Australian Government entered into negotiations to establish a new framework for collection centres. It was decided that any new arrangements should:

- assure quality of, and access to, collection centres;
- reduce government regulation and associated restrictions on competition;
- allocate collection centres between APA's based on activity and performance of the individual APA;

[21] Regulatory Impact Statement – New accreditation arrangements for pathology specimen collection centres, Department of Health internal report.

- balance access, cost and affordability, and allow industry to adjust to new arrangements;
- allow both public and private sector service providers access to the scheme;
- simplify the administrative arrangements; and
- promote accountability and transparency.

Accordingly, the ACC scheme replaced the LCC scheme on 1 December 2001 and was gradually phased in to full implementation on 1 July 2005.

To apply for approval to operate a collection centre, both the premises and the APA must meet eligibility criteria as set out in the *HIA* and the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* (‘*the Collection Centre Approval Principles’*).

The current approach to licensing ACCs is similar to the LCC scheme, essentially having two components:

- the requirement for accreditation; and
- the restriction on the number of ACCs operated by each APA.

Accreditation

The NPAAC *Standards for Pathology Laboratories* establishes standards relating to the pre-analytical phase. This requires:

> Collection of specimens should be performed in appropriate facilities and under appropriate conditions. Specimen collection, specimen transport and processing must preserve the quality and integrity of the specimen in a manner appropriate to the proposed testing.[22]

In practice, NATA will inspect one collection centre per laboratory assessment to assess this standard. Anecdotal evidence indicates this is generally a collection centre close to the laboratory.

The NPAAC *Guidelines for Approved Pathology Collection Centres 2006* lists the minimum requirements to apply to collection facilities utilised in the collection of samples for Medicare-billed testing in accredited pathology laboratories.[23] These guidelines also stipulate that the:

> Assessment of collection centres may be performed as part of the assessment of laboratories by NATA / RCPA.[24]

[22] Standard 5
[23] Clause 1.2
[24] Clause 1.3

And that:

> There will be an annual self-assessment (subject to random or purpose-based Medicare Australia assessment of compliance) as part of the annual ACC application to the organisation.[25]

The Guidelines provide minimum standards regarding:

- premises;
- equipment;
- materials;
- staffing;
- documentation / instruction;
- health and safety;
- safety and waste disposal; and
- collection, storage and transport of specimens.

On renewal of collection centre licences, APAs must complete a self-assessment of the premises for compliance with the NPAAC collection centre guidelines. However, stakeholders have indicated that while Medicare has the scope to perform random audits of collection centres, in practice this rarely, if ever, happens.

In 2001, the profession and the Government entered into discussions about collection centre accreditation, amid concerns that too many of these premises were not being assessed. The profession indicated that NATA assessment of each individual collection centre would be costly, with anecdotal evidence indicating a fee of around $1,000 per collection centre would apply. Should the Government adopt this approach, the profession sought some form of subsidy to compensate them for at least part of the additional expense.

As a compromise, the Government investigated the possibility of performing compliance checks themselves with the Health Insurance Commission (HIC) undertaking a trial audit of collection centres. KPMG understands that the findings of the trial audit were provided to the Pathology Consultative Committee (PCC) for consideration.

[25] Clause 1.4

Restriction on ACC numbers

The maximum number of ACCs an APA may operate is dependent on:

- the category of the APL it owns / operates;
- the length of time it has owned/operated the APL (referring to temporary floor of two licences and the grandfathered provisions from the LCC scheme as outlined on the page overleaf); and
- the number of patient episodes[26] for which the APA provided a pathology service during the relevant calendar year.

The rules for maximum number of collection centres operated by an APA are outlined in Table 4 below.

Table 4: Maximum number of collection centres permitted

Laboratory category	ACC rules	Exceptions
Category GX & GY (General)	For every 14,200 patient episodes an APA obtains an additional licence to operate another ACC.[27]	APAs may convert a licence entitlement into 3 ACCs if situated in rural / remote areas.[28] The 'plus one' rule enables an APA to increase by one its maximum ACC entitlements for each ACC co-located with the Category GX or GY laboratory (i.e. a 'free' ACC).[29] Start-up APAs receive a minimum 2 licences for the first 2 years of operation. This is a temporary floor after which the APA must generate patient episodes to justify its ACCs.[30]
Category B (Branch)	Category B laboratories are not mentioned in the ACC principles.	None
Category M (Medical)	Category M laboratories are not mentioned in the ACC principles.	None

[26] A patient episode comprises pathology services specified in one or more items which are provided for a single patient, the need for which was determined under the Act on the same day. This is irrespective of whether they were provided by one or more APPs on one day or over several days and whether they are requested by one or more treating practitioners.
[27] See cl.11(2)(a) and cl.12(3)(a) of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005*.
[28] See cl.10 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005*.
[29] See cl.11(3) and cl.12(4) of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005.*
[30] See cl.12(2) of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005.*

Laboratory category	ACC rules	Exceptions
Category S (Specialised)	For each Category S laboratory, the APA may operate 1 ACC on the same premises.	APAs can operate ACCs for Category S laboratories that were operating under the LCC scheme immediately prior to the ACC scheme. These entitlements were grandfathered to prevent losses resulting from changing schemes.[31]

Source: *Health Insurance (Eligible Collection Centres) Approval Principles 2005.*

4.2 Funding arrangements

Funding for pathology testing is generally provided through three ways: through Medicare, on a fee-for-service basis or to public hospital inpatients from State and Territory governments. While approval as an ACC is essential for Medicare-eligibility, it is unlikely that Medicare funding is the sole source of revenue funding as only a proportion of the estimated costs are paid by Medicare and there are a range of tests which are not included on the MBS. Other funding sources include private health insurers, Workcover and the Transport Accident Commission in Victoria.

4.2.1 Medicare Benefits Schedule

The Medicare Benefits Schedule ("the Schedule") lists the fees determined by the Government for the purpose of paying benefits under Medicare. Category 6 of the Schedule contains the Pathology Services Table (PST), which relates specifically to the pathology tests for which Medicare benefits are available and the corresponding fees.

4.2.1.1 Fee for service

The majority of the items listed in the PST relate to the fees for specific services across the range of pathology disciplines. The rebate is currently 75 per cent of the MBS fee for in-hospital pathology services (where the patient is not a public inpatient), and 85 per cent of the MBS fee for pathology services rendered out of hospital.

Patients who are bulk-billed do not incur any out-of-pocket expense for pathology services. For patients that are not bulk-billed it is at the providers' discretion whether to privately bill the patient for the gap or incur the gap themselves. This is essentially an organisational decision, with some providers incurring this gap in order to compete on price, while others will pass on the remaining cost to the consumer and compete on reputation and service quality alone.

Two rules that affects the fee for pathology service relates to 'episode coning' and the 'multiple service rule' (MSR). Broadly the coning rule applies to Medicare benefits payable for a patient episode containing more than three items where the benefits paid are limited to the sum of the three items with the highest MBS fees. Exceptions to the episode coning rule include pathology

[31] See cl.5(2)(c) of the Health *Insurance (Eligible Collection Centres) Approval Principles 2005.*

services requested by specialists, pathology services rendered for hospital in-patients and particular MBS pathology items. The MSR rule applies where multiple instances of certain tests have been requested in a single episode such that the benefits paid taper off and are not paid beyond a certain number of tests.

4.2.1.2 Patient episode initiation fee

One form of fee provided for in the PST is a patient episode initiation (PEI) fee.[32] The PEI was introduced in 1992. The PEI was not intended to cover the cost of the actual test itself, but rather:[33]

- the overhead costs of the collecting centre;
- staff and equipment;
- transport costs between the patient, collection centre and laboratory;
- storage facilities; and
- quality control, LCC inspection and licensing.

The current PEI fee for specimens collected in accredited collection centres is $17.40, of which patients attending accredited collection centres receive 85 per cent, amounting to $14.80.[34]

However, the *Health Insurance (Pathology Service Table) Regulations 2005* stipulates that the PEI does not apply for services rendered by a public hospital / public laboratory.[35]

The current MOU provides for the phased introduction of PEI fees for public sector accredited pathology laboratories, which will be introduced on 1 May 2007 at $2.40 per item (subject to the appropriate Parliamentary processes).[36]

4.2.2 Memorandum of Understanding

In 1996-97, the Australian Government entered into an agreement with the AAPP and the Royal College of Pathologists of Australasia (RCPA) to cap Medicare outlays on pathology services to a growth rate of 6 per cent per annum over the three years to 1998-99.[37] The agreement provided for an automatic reduction in the fee for service under Medicare if the measures implemented did not contain growth in expenditure.

[32] Category 6, Group 10 of Medicare Benefits Schedule.
[33] Directions for Pathology, 1997-98, Internal Department of Health report.
[34] Category 6, Group 10 of Medicare Benefits Schedule
[35] Section 14(2).
[36] Pathology Quality and Outlays Memorandum of Understanding, 2004
[37] The Agreement enables management of growth in pathology outlays under the Medicare benefits arrangements, within agreed expenditure patterns, by providing for downward adjustment of unit price as aggregated expenditure varies beyond defined limits. As a consequence, public outlays are maintained within defined limits.

This agreement was subsequently extended until June 2004, which provided for a target growth rate in Medicare outlays relating to pathology services of 5 per cent. In 2005, a third pathology funding agreement was entered into with the AAPP, the RCPA and the National Coalition of Public Pathology (NCOPP) for the period 1 July 2004 to 30 June 2009, being the Pathology Quality and Outlays Memorandum of Understanding (MOU). The MOU provides for target growth rates in Medicare outlays of ranging between 4.6 per cent per annum and 5.8 per cent per annum over the duration of the agreement.[38]

The Pathology Consultative Committee (PCC) is the body responsible for managing the MOU and providing policy advice to the Minister for Health and Ageing regarding its operation. PCC membership comprises AAPP, RCPA, NCOPP and the Department of Health and Ageing (DoHA) representing the government.

Outlays under the MOU are currently exceeding the agreed growth targets. The signatories to the MOU are in the process of negotiating options for adjustments.[39]

4.3 Summary of pathology regulations

The following table provides a profile/comparison of the different regulatory requirements governing the pathology profession.

Table 5: matrix of regulatory requirements

Regulatory requirements	APA	APP	APL	ACC
Licensing	✓	✓		✓
Accreditation			✓	✓
Professional qualifications	✓	✓	✓	✓
Restrictions on number				✓
Fee/tax	✓	✓	✓	✓

As shown above there is a noticeable degree of overlap in regulatory requirements along the service path continuum. Given that a major aim of the NCP legislative review process is to reduce duplication and overlap in regulation in order to avoid unnecessary compliance costs and restrictions to competition, any assessment of the current regulation of ACCs will need to consider whether the regulatory arrangements for APAs, APPs and APLs are already meeting the objectives of regulating ACCs.

[38] Clause 5.
[39] Correspondence from Department of Health and Ageing, 7 June 2006.

5 The appropriateness of the current regulatory arrangements

The chapter summarises development in the regulation of ACCs and identifies competitive restrictions in the current regulatory arrangements.

5.1 Objectives of regulating pathology collection centres

As the historical origins of the ACC scheme implies, the objectives of the regulations are somewhat mixed. There is no explicit statement of underlying objectives of the ACC arrangements, but review of literature and discussions with key stakeholders have revealed a range of historical reasons for regulating collection centres. For example, as previously outlined in section 4.1.5.1 KPMG understands that the aims of the LCC scheme were to:

- reduce the number of collection centres by limiting the number of LCCs;
- increase the efficiency of pathology specimen collection;
- ensure that future growth of collection centres occurred in an orderly manner;
- ensure that all collection centres were of a reasonable standard; and
- allow flexibility to the industry to make decision on whether to apply for units of entitlement and licences, and the number and location of collection centres. [40]

Similarly, as outlined in 4.1.5.2 the ACC scheme aimed to:

- assure quality of, and access to, collection centres;
- reduce government regulation and associated restrictions on competition;
- allocate collection centres to APAs based on activity and performance of the individual APA;
- balance access, cost and affordability, and allow industry to adjust to new arrangements;
- allow both public and private sector service providers access to the scheme;
- simplify the administrative arrangements; and
- promote accountability and transparency.

In recognising that the landscape has changed somewhat since the first introducing the LCC, and more recently introducing the ACC, an important role for KPMG has been to establish the future objectives for regulating collection centres. Through the broad circulation of a

[40] Review of the LCC Scheme, Background information and issues for discussion, PCC 37, 1998.

Discussion Paper and during stakeholder consultation KPMG posed the question "What are the objectives of regulating ACCs?" The most commonly cited objectives related to:

- Quality control - many stakeholders emphasised that maintaining the quality of pathology services is essential. While recognising that all phases of the pathology testing process are important, the pre-analytical phase was specifically identified by a number of stakeholders as critical to the testing process.[41]

- Cost reduction – stemming from the historical objectives of the LCC and ACC schemes a large number of stakeholders believe that collection centres should be regulated to help contain industry costs, and hence the cost to government (i.e. in line with the MoU).

- Patient access – providing access to pathology collection centres, not only in regional and rural areas, but also outer metropolitan areas was also highlighted as an important objective of regulation collection centres.

- Business conduct – ensuring pathology service providers compete on equal and commercial grounds was emphasised as a basis for regulation. Numerous reports of providers paying well above market rents for collection centre premises were provided during consultation as a testament to this. This particular issue is addressed in the Phillips Fox Review,[42] parts of which have been taking place concurrently with this NCP review.

Other objectives included creating a level playing field for all participants, promote efficiency and competition and allowing access for new entrants.

5.2 The appropriateness of current objectives

The Council of Australian Governments has stated that government interventions in markets should be restricted to incidences of market failure and that each regulatory regime should specifically target the specific market failure/s. Major causes of market failure include:

- *Information asymmetries* - consumers may not have adequate access to the information they need to make informed, objective decisions about the quality of products and services, and the service providers that supply them.

- *Externalities* - an externality refers to an action taken by a market participant that has consequences for other market participants which are not reflected in a market price. Negative externalities impose costs on other parties (e.g. a factory polluting a river and negatively impacting on the local community's enjoyment of the river) where as positive externalities provide benefits for other parties (e.g. flu vaccination of one person which lowers the chance of contracting the virus and passing it on to others).

[41] For example, a member of the PCC claimed that the pre-analytical phase is the most important phase of testing because it is where the greatest errors occur.
[42] Phillips Fox, 2005, *Review of Enforcement and Offence Provisions of the Health Insurance Act 1973 as they Relate to the provision of Pathology Services Under Medicare.*

- *Where natural monopolies exist* - the cost of one firm providing the service is less than the cost of two or more competing firms. In this case a natural monopoly is considered socially optimal, but requires regulation to ensure that it does not use its monopoly power to exploit its customers.

- *Public goods* – these goods have two defining characteristics – they are non-excludable (that is, providers can't stop others using them) and non-rivalrous in consumption (that is, the consumption by one person does not diminish their availability for the next person). Defence is the most commonly cited example of a public good.

Governments do not normally communicate objectives in terms of market failures or social equity, but will instead rationalise government intervention in terms of:

- *The desire for universal access to goods and services*;

- *The allocation of public resources*; *and*

- *The protection of consumers, human health and the environment*.

After careful consideration of historical information, discussions with stakeholders and the Department, KPMG considers that, to some extent, market intervention could be justified in terms of all of the above, specifically:

- Access to pathology collection services – providing access to pathology collection services is essential to ensuring high quality health outcomes for society.

- Protection of consumers and human health – without sufficient quality controls on collection centre the risk of errors in the overall testing process will be greater. This has implications for consumers and human health.

- Allocation of public resources – as outlined in section 4.2.2 the pathology industry operates under a MoU which provides for target growth rates of between 4.6 per cent and 5.8 per cent over the life of the agreement. Given that the pathology testing is predominantly funded by the public purse the government has an interest to ensuring that the funding is allocated in an efficient and effective manner.

These broadly translate to the following objectives:

- Timely patient access to quality pathology services;

- A sustainable, competitive, and efficient industry; and

- Contribute to the management of outlays under a capped agreement.

While stakeholders emphasised that 'cost reduction' should be an explicit objective of regulation KPMG does not consider, given the objectives of NCP, this is a sufficient rationale for regulation. Hence cost reduction is not an appropriate objective of regulating ACCs.

5.3 Competitive restrictions of the ACC arrangements

The following tables summarise the restrictions to competition contained in the legislative framework for approved collection centres. The legislative instruments reviewed were:

- *Health Insurance Act 1973*;
- *Health Insurance (Eligible Collection Centres) Approval Principles 2005*;
- *Pathology Quality and Outlays Memorandum of Understanding (MOU).*

Table 6: Identified competitive restrictions

Section No	Description
Health Insurance Act 1973	
4A	The regulations may prescribe a table of pathology services that sets out the following: (a) items of pathology services; (b) the amount of fees applicable in respect of each item; and (c) rules for interpretation of the table. ***This is effectively a price control***
16(A)(5AAA)	This section restricts the payment of Medicare benefits for a pathology service to that for which the specimen was collected by specific people and at specific places (i.e. no payment if not collected by a specified person at a specified place, including approved collection centres). ***It restricts eligibility to Medicare benefits, and effectively establishes a preferred means for specimen collection***
23DNBA(1)	The Minister may grant an approval to an approved pathology authority for an eligible collection centre conducted (or to be conducted) on premises of which the authority is the owner, lessee or sub-lessee. ***This is effectively a licensing/accreditation scheme. Note: the licensing arrangements for APAs may effectively place restrictions on business structure, form or ownership***.
23DNBA(2)	The Minister must not grant an approval for an eligible collection centre unless the tax on that grant has been paid. Tax on the grant of an approval is imposed by the Health Insurance (Approved Pathology Specimen Collection Centres) Tax Act 2000. ***This is effectively a licence fee. The "tax" is $1,000 per annum (pro rata for part thereof).***
23DNBB(3)	Any document issued by or on behalf of the APP operating an ACC and relating to the collection of a specimen at the centre or the sending of the specimen to an accredited pathology laboratory, must specify the ACC's unique identification number.
23DNG(1)	An approval for an ACC may be revoked under certain circumstances, including failure to comply with the Collection Centre Guidelines (if such are provided for in the Approved Principles – see s.23DNBA(5)). ***The Guidelines themselves may contain anti-competitive restrictions.***

Section No	Description
23DNK(1)	The ACC must display a notice that it is an approved ACC in a prominent place that is visible when the centre is open or closed. There are exceptions to this under 23DNK(2).
23DNL(1)	If not an ACC, the centre must inform the patient and the APP by whom the pathology service is to be rendered that a Medicare benefit would not be payable for the pathology service. ***It restricts eligibility to Medicare benefits, and effectively establishes a preferred means for specimen collection.***
Health Insurance (Eligible Collection Centres) Approval Principles 2005	
5(1)	An application for approval of an eligible collection centre must not be considered by the Minister unless it is made: (a) by an APA who is an eligible applicant; and (b) in writing and in the prescribed form. ***This restricts who may apply for approval of a collection centre.***
5(2)	An APA is an eligible applicant if they: (a) operate and are the sole owner of a category G accredited pathology laboratory (APL); or (b) have an agreement with another APA for the use of a category G APL located in rural or remote statistical divisions (but not at a hospital); or (c) operate and are the sole owner of a category S APL, and immediately before the commencement of item 31 of the amendment act, was the holder of a unit of entitlement to operate a licensed collection centre; or (d) operates, and is the sole owner of, an accredited pathology laboratory that is a category S pathology laboratory that: (i) is proposing to collect solely specimens within its speciality; (ii) will be located on the same premises as the collection centre that is the subject of the application; and (iii) received accreditation as a category S laboratory after the commencement of item 31 of Schedule 1 to the Amendment Act. ***This restricts who may apply for approval of a collection centre. Effectively, the applicant also has to meet the requirements for approval of an APL, which are set out in Health Insurance (Accredited Pathology Laboratories – Approval) Principles 2002.***
9(2)	The applicant must be granted the maximum number of approvals to which the applicant is entitled under this Part.

Section No	Description
11(2)	For an APA that operates and is the sole owner of a category G APL, and has operated an APL for 2 full consecutive calendar years: Subject to subsection (3), the maximum number of approvals that the APA may be granted under this section is determined by dividing, by 14 200, the number of patient episodes for which the APA provided pathology service(s) during the calendar year immediately preceding the calendar year in which the relevant financial year commences. The resulting number is rounded to the nearest whole number. ***This sets a quota on the number of licences an APA may hold.***
11(3)	For an APA that proposes to operate an ACC in the same premises as it operates a category G APL in the relevant financial year, the maximum number of approvals is increased by one for each ACC centre that it proposes to operate in the same premises as it operates a category G APL.
12(2)	For an APA that operates and is the sole owner of a category G APL, and has NOT operated an APL for 2 full consecutive calendar years: Subject to subsection (4), the maximum number of approvals that the APA may be granted under this section is: (a) if the APA has operated, and been the sole owner of, a category G APL for less than the full calendar year immediately preceding the calendar year in which the application for approval is made – 2; or (b) if the APA has operated, and been the sole owner of, a category G APL for the full calendar year immediately preceding the calendar year in which the application for approval is made, but less than the period mentioned in paragraph 11 (1) (b) – the higher of 2 and the number determined by dividing, by 14 200, the number of patient episodes for which the APA provided pathology service(s), during the calendar year immediately preceding the calendar year in which the relevant financial year commences. The resulting number is rounded to the nearest whole number. ***This sets a quota on the number of licences an APA may hold.***
12(4)	For an APA that proposes to operate an ACC in the same premises as it operates a category G APL in the relevant financial year, the maximum number of approvals is increased by one for each ACC that it proposes to operate in the same premises as it operates a category G APL.
13	Applicants relying on an arrangement with the owner of a category G pathology laboratory and who operate collection centres in rural or remote areas: The maximum number of approvals that may be granted to an APA to which paragraph 5(2)(b) applies is the number that is equal to the number of specimen collection centres that: (a) the APA was operating immediately before the commencement of item 31 of Schedule 1 to the Amendment Act; and (b) were not located on the hospital premises of a recognized hospital. ***This sets a quota on the number of licences an APA may hold.***
14	Applicants operating a category S pathology laboratory who held section 23DNB units: The maximum number of approvals that may be granted to an APA to which paragraph 5(2)(c) applies is the number that is equal to the number of licensed collection centres that the APA was operating immediately before the commencement of item 31 of Schedule 1 to the Amendment Act. ***This sets a quota on the number of licences an APA may hold.***

Section No	Description
15	Applicants operating a category S pathology laboratory who have not held section 23DNB units: The maximum number of approvals that may be granted to an APA to which paragraph 5(2)(d) applies is one for each of the premises on which the APA operates a category S pathology laboratory of the kind described in paragraph 5(2)(d). ***This sets a quota on the number of licences an APA may hold.***
16	If an APA (the acquiring APA) acquires business from another APA to which an approval has been granted, the acquiring APA may request the Minister to confirm the transfer of the approval to the acquiring APA from a specified date, not earlier than 2 weeks after the Minister receives the request. ***Imposes restrictions on business ownership.***
17(2)	If an APA to which an approval has been granted merges business with another APA, the merged business may request the Minister to confirm that the approval is effectively held by the APA resulting from the merger. ***Imposes restrictions on business ownership.***
18	An undertaking given by an applicant under paragraph 5 (3) (b) must include an undertaking to give to the Health Insurance Commission (i.e. Medicare) written notice within 24 hours after a failure to comply with the Collection Centre Guidelines in operating an approved collection centre, including an explanation of the reason for the non-compliance.
Pathology Quality and Outlays Memorandum of Understanding	
5.1	This section sets out the agreed annual funding for pathology services (i.e. those covered by Medicare). ***Provides a funding cap, not related to volume***
7.1, 7.17	The Pathology Services Table Committee determines the rates for pathology services, which are then included in the Medicare Benefits Schedule (MBS). ***Sets the charges for pathology services (or at least the Medicare benefit attached to them).***
Guidelines for Approved Pathology Collection Centres	
2 – 9	These section sets out minimum requirements ACCs, including: • premises • equipment • materials • staffing (including minimum training) • documentation/instruction • health and safety • safety and waste disposal • collection, storage and transport of specimens.

KPMG has conducted a preliminary review of the above competitive restrictions. As some of these restrictions are minor in nature, their impact is likely to be minimal. On the other hand, there are a number of restrictions which warrant further investigations, including:

- ss.4A and 16(A)(5AA) and 23DNBA(2) of the *Health Insurance Act 1973;*
- cl.5(1), 5(2), 11(2), 11(3), 12(2), 12(4), 13, 15 and 16 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005*; and
- the Guidelines for Approved Pathology Collection Centres.

These restrictions are analysed in depth in the following chapters.

6 What is the most appropriate form of regulation?

Licensing is a common form of regulation, used as a means of prohibiting certain activities unless provided by approved (i.e. licensed) individuals or organisations. This chapter considers the appropriateness of licensing collection centres as well as other alternative forms of regulation.

6.1 The costs and benefits of the current licensing regime

There are a number of well-recognised costs and benefits associated with a traditional or 'positive' licensing regime.

6.1.1 Costs of licensing collection centres

Costs associated with a licensing regime may broadly be classified as:

- *administrative costs for government;*
- *compliance costs for industry*; and
- *costs to economic efficiency* arising from restrictions to competition.[43]

These costs are discussed below.

6.1.1.1 Costs of administration

To administer effective licence schemes, the Government incurs direct financial costs in designing, implementing, administering and enforcing the regulations. Furthermore, Australian Governments are obliged to review and update regulations in order to meet their responsibilities under NCP principles and other government initiatives, thus periodically incurring direct financial costs beyond the ongoing administration and enforcement of the licensing scheme.

6.1.1.2 Compliance costs

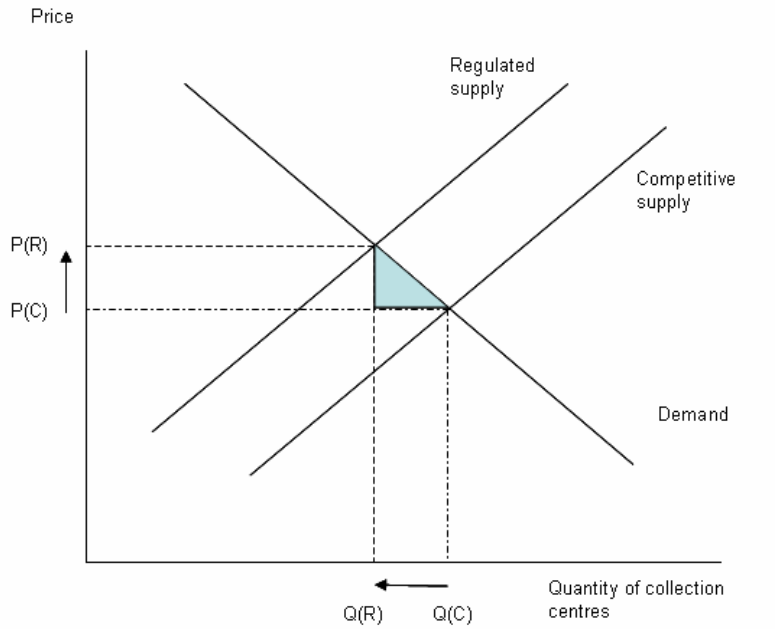
Compliance costs to businesses in a licensed industry arise from several sources. Firstly the business must purchase the licence and conform to the conditions of that licence, potentially requiring necessary investment in infrastructure and equipment. This will generally also include maintaining records for periodic reporting to the regulator and requires trained management and staff to undertake these necessary tasks to continue operation. Management may also seek advice from external experts (such as lawyers and auditors) to ensure their business operations comply with the licence conditions.

[43] Regulation Taskforce, Rethinking regulation: Report of the Taskforce of Reducing Regulatory Burden on Business, Report to the Prime Minister and the Treasurer, London, 2006.

6.1.1.3 Costs to economic efficiency

In theory, licensing regimes have an impact on economic efficiency.

Figure 11: Losses to economic efficiency from licensing



The above diagram illustrates the loss in efficiency resulting from licence regimes. In a competitive environment, the equilibrium quantity of collection centres is represented by Q(C) at a price of P(C). The imposition of the licensing regime limits the allowable supply of collection centres, as represented by the leftward shift of the supply curve. This results in restricted output of Q(R) and a higher price of P(R).

The shaded triangle is termed a 'deadweight loss', which represents the loss in efficiency resulting from a move from free market entry to regulated supply. This arises because there are a number of providers who would be prepared to pay between the competitive price P(C) and the restricted price P(R), but are restricted from entering the market.

The potential negative consequences of a licensing regime also include the following.

Barriers to entry

The requirement to be licensed creates barriers to entry for potential new industry players. These barriers may be in the form of:

- The cost of the licence itself;
- The cost of initial compliance with licence conditions (i.e. quality standards may require industry players to establish certain infrastructure and possess specific equipment); and

- The existence of quotas on the numbers of licences may completely restrict entry to the market or restrict the extent to which the start-up business may participate in the market.

Barriers to entry restrict competition in the industry, which reduces the incentive for incumbent providers to decrease costs and pass these cost savings onto consumers to secure their market share. Furthermore as barriers to entry limit the number of market participants and suppresses incentives to innovate and differentiate from other providers, it also results in fewer choices for consumers.

Restrictions to entry may also enhance the market power of incumbent providers. This may redistribute wealth in their favour and is particularly likely when licences involve explicit or implicit quotas on the numbers of businesses which may engage in the licensed activity.

Imposition of required behaviours

The imposition of required behaviours, such as undertaking necessary tasks to comply with licence conditions, diverts management and staff attention away from their core business. A submission to the Australian Government Taskforce on Reducing Regulatory Burdens on Business indicated:

> The economic cost of complying with regulations is a key determinant of national competitiveness and the investment environment for businesses. These costs can be direct, such as capital and operating costs. They can also be indirect, that is, opportunity costs, where the principals of the businesses are taken away from their strategic roles of driving innovation, securing investment and increasing productivity.[44]

Therefore the cost of complying with licence conditions may also include lost opportunities to increase innovation and economic efficiency.

Without considering quality aspects, in theory those stakeholders which generally gain from removing licensing requirements include:

- Consumers – who would expect to pay lower prices; and

- Potential providers – who would find it easier (i.e. less costly in time and effort) to enter the market.

6.1.2 Benefits of licensing collection centres

Benefits of licensing can be broadly classified as:

- *Greater certainty regarding the quality of products and services supplied* – the licensing of collection centres provides consumers with the reassurance that they meet minimum quality standards (eg, NPAAC standards);

[44] Regulation Taskforce, *Rethinking regulation: Report of the Taskforce of Reducing Regulatory Burden on Business,* Report to the Prime Minister and the Treasurer, London, 2006.

- *A reduction in consumer risk* – minimises the risk to patients due to qualified professionals and standards of service; and

- *A reduction in enforcement costs* – mandatory disclosure of information provides ease of access to business information, increases business compliance and reduces the costs of enforcement.

These benefits, as well as the benefits stemming from the current licensing arrangements are discussed in turn below.

6.1.2.1 Reduced consumer risk

Licensing provides a mechanism by which conditions can be imposed (i.e. licence conditions) and hence minimises the risk to consumers that products / services in the market are erroneous and defective. This may be ensured through:[45]

- Occupational licensing – restricting market entry to persons with particular qualifications, thus ensuring suppliers of goods / services possess the necessary skills and knowledge. In the pathology industry, APPs must be medical practitioners.

- Professional licensing – requiring persons to be licensed professionals in order to perform the licensed activity (despite having the appropriate qualifications). This may include imposing standards of practice and business independence to ensure ethical conduct and eliminate personal conflicts of interest. In the pathology industry, providers must be APPs to perform Medicare-eligible tests.

- Business licensing – requiring the actual business to be licensed which may impose additional regulations regarding:

  - The business premises to ensure the goods / services are supplied in quality controlled environment (such as establishing APLs and ACCs in the pathology industry); and

  - The business management to ensure managers / directors that fall outside the scope of the profession are also accountable to ethical standards (such as establishing APAs in the pathology industry).

6.1.2.2 Greater certainty

Licensing provides consumers with the reassurance that the products / services supplied by licensed businesses meet minimum quality standards (e.g. NPAAC standards in the pathology industry). This is particularly important in the health industry given the community's expectation that the health system will provide those products / services that are effective in the prevention and treatment of injury, illness and disease.

[45] Deighton-Smith, R., Harris, B. and Pearson, K. 2001, *Reforming the Regulation of the Professions*, National Competition Council Staff Discussion Paper, AusInfo, Canberra. Found at: http://www.ncc.gov.au/pdf/PIReStPr-001.pdf. Accessed on: 11/06/06.

6.1.2.3 Reduced enforcement costs

Mandatory disclosure of information by licensees as part of licence conditions provides regulators with ease of access to business information and encourages business compliance with the licence conditions. Access to information and fewer cases of non-compliance will reduce the costs of enforcement to the Government. Note that this benefit assumes there is justification for some form of industry regulation, and the enforcement of a licensing scheme is potentially more cost-effective than other forms of regulation that do not impose mandatory information disclosures.

6.1.3 Who gains from removing licensing conditions?

Without considering quality aspects, in theory those stakeholders that generally gain from removing licensing requirements include:

- Potential providers – who would find it easier (i.e. less costly in time and effort) to enter the market and compete; and

- Consumers – who would expect to pay lower prices and enjoy wider choices as providers compete for market share.

6.2 Alternative approaches to regulation

This section explores a number of different approaches that could be employed in place of, or possibly in conjunction with, licensing.

6.2.1 Self regulation

Self-regulation is the means by which members of a profession, trade or commercial activity govern the activities of members. Members are bound by a mutually agreed set of rules, which may be accepted voluntarily or by compulsion. There are usually sanctions for non-compliance.

Industry has an array of self-regulatory options available to address specific problems and objectives, including codes of conduct, industry service charters, guidelines and standards, as well as industry-based accreditation and complaint handling schemes.

There are different reasons for establishing self-regulatory schemes. For example, industries may choose to self-regulate to promote consumer confidence or to avoid other forms of more heavy handed regulation.

There are a number of benefits of self-regulation, most notably:

- industry flexibility — self regulation allows for industry participants to easily respond to changes in the nature of the industry (eg, changing technologies and/or consumer preferences);

- industry experience – self regulation draws heavily on industry experience, which can be important in highly technical industries; and

- cost reduction – self regulation generally imposes lower compliance costs on business and reduces administration and enforcement costs to government.

Self-regulation is generally considered appropriate when:

- there is sufficient power and commonality of interest within an industry to deter non-compliance;

- there is no strong public interest concern, in particular, no major public health and safety concern;

- the problem is a low risk event, of low impact/significance; and

- the cost of non–compliance must be small.

Over the course of the review it has become clear that, despite the presence of an industry association, there is significant disparity in the views of large and small and medium providers. Given the polarisation of views within industry, and the high levels of industry concentration (previously highlighted in section 3.1.4), KPMG does not consider self-regulation to be a viable alternative at this time.

6.2.2 Co-regulation

Co-regulation is a situation where the government and market / industry participants work together to achieve a regulatory system. The influence of the government in this case is distinguished from that of direct regulation - the industry participants are responsible for creation of suitable regulations, which may then be administered by the government.[46]

Common examples of conventions in this setting are Codes of Conduct.[47] Developed and administered by the industry itself, these may be given legislative authority, for example through the provisions of the *Trade Practice Act*, depending on the structure and desire of participants and the potential impact of externalities. Examples include the Franchising Code of Conduct, the Medicines Australia Code of Conduct and the Code of Conduct for Patent and Trade Marks Attorneys.

Co-regulation has been described as self-regulation with a legislative backstop.[48]

Particularly in the pathology industry, accreditation inspections and audits by co-regulators are probably more effective than those by government agencies because members of the industry

[46] Department of Treasury and Finance, *Victorian Guide to Regulation*, Melbourne, 2005, p B2.
[47] Bureau of Industry Economics, *Business licences and regulation reform*, Report 96/10, AGPS, Canberra, 1996, p.44.
[48] Better Regulation Taskforce (UK), *Routes to better regulation - a guide to alternative to classic regulation*, London, December 2005, p.26.

are better placed to detect breaches of compliance and cover-ups than government inspectors. The members of the pathology profession have a better knowledge of the quality of services they provide so that the profession itself has the best capacity to control service quality and identify low standards.

Nonetheless, in theory there is the potential risk of co-regulators using their powers to restrict entry for the benefit of existing members. That is, there is a chance that licences may be restricted in order to reduce competition and increase protection for incumbent industry participants. Also, there is the question of who is responsible for enforcement in highly concentrated markets.

Co-regulation is generally considered to be effective when:

- there is a public interest in some government involvement in regulatory arrangements, and the issue is unlikely to be addressed by self-regulation;
- where professional independence is a major consideration; and
- when there are advantages in the government engaging in a collaborative approach with industry, with industry having strong ownership of the scheme, which will require:
  - a specific industry solution rather than regulation of general application;
  - a cohesive industry, where incentives and interests are aligned; and
  - a strong industry association with broad coverage. [49]

Despite meeting the majority of the key criteria listed above, including a strong industry association with relatively broad coverage, as discussed previously, stakeholder consultation revealed a clear polarisation of views within industry. KPMG is concerned over the significant disagreement between the large providers and the medium and small providers and therefore does not consider co-regulation to be viable option at this point in time.

6.2.3 Certification

Certification or accreditation amount to non-mandatory licences. They involve prior approval and compliance with minimum standards, with accreditation being withdrawn for failing to satisfy the standards. Accreditation schemes may operate in conjunction with or instead of a licensing scheme. Many critics of licensing systems favour accreditation as an alternative.[50]

Hence, certification can decrease consumer search costs, particularly where a significant degree of search would otherwise be required to obtain information about the qualifications, expertise,

[49] Department of Treasury and Finance, *Victorian Guide to Regulation*, Melbourne, 2005, p B2.
[50] Bureau of Industry Economics, *Business licences and regulation reform*, Report 96/10, June 1996, p.7.

etc of a provider. Certification also serves to create consumer and patient confidence that the services being performed are done so by a professional.[51]

Certification is an area of regulation that could be performed by the industry itself. As discussed above, the industry has the potential to detect breaches of compliance and cover-ups in a more precise and efficient manner than government inspectors.

The major advantage of certification or accreditation schemes over licensing are the minimum standards imposed are able to cover the same requirements as found in a traditional licence based approach. This avoids the downside of licences, such as waste of resources and competition restrictions while maximising the consumer and industry confidence gained by setting minimum operating standards.

As noted previously in section 4.1.5 there is a currently a scheme for the accreditation of ACCs.

6.2.4 Negative licensing

Under negative licensing schemes, an individual or business is permitted to undertake a commercial activity without any test of competence. However, if it is subsequently determined by an agency that the business has failed to meet a minimum quality or performance standard, the right to conduct the activity may be withdrawn. [52]

Negative licensing can take two forms, both of which may require the payment of a licence fee. That is, where there are:

- no entry requirements necessary to get a licence (ie, just sign up by providing contact information); or

- restrictions on entry based on certain negative characteristics (eg, serious criminal convictions) rather than specification of any positive requirements for licensing (eg, good character or particular professional requirements).

Advantages of negative licensing may include:

- lower administrative costs — the costs of administering a negative licensing system are much lower than that of positive licensing resulting in a small net saving to the Government; and

- lower compliance costs — relative to positive licensing, negative licensing is likely to impose fewer costs on collection centres which should result in lower prices for consumers; and

- the ability to 'punish' contravention of licence conditions — the threat of licence revocation may give providers incentive to provide high quality services, in situations where

[51] The Taskforce on Industry Self Regulation, *Industry Self-Regulation in Consumer Markets*, Canberra, August 2000, p 28.
[52] Bureau of Industry Economics, *Business licences and regulation reform*, Report 96/10, June 1996, p.22.

registration alone may not be enough. This amounts to a system of free entry and enforced exit.

The costs of negative licensing are that it:

- may reduce competition as high minimum standards deter new entrants; and
- its application is limited where there are no significant public health and safety concerns.

Negative is licensing is considered most appropriate when:

- there is no major public health and safety concern; and
- the problem is of relatively low risk in terms of its impact and significance.

As negative licensing effectively screens-out poor quality suppliers 'after the fact', it is generally not considered appropriate where there are significant public health and safety concerns. Consequently KPMG does not believe that negative licensing is an appropriate means of regulating ACCs.

6.3 Regulation of other professions

6.3.1 Licensing in the radiology industry

The radiology industry shares many similarities with the pathology industry in terms of its nature and structure. Both industries:

- require their service providers to have a written third party referral from another medical practitioner;
- have similar funding arrangements with the Federal Government in the form capped funding via a Memorandum of Understanding (MoU); and
- are characterised by a similar industry structure and competitive environment.

The State Governments are responsible for licensing and setting industry quality standards. For example, State Health Acts regulate the:

- registration and licensing of x-ray clinics;
- registration of equipment to ensure that it meets certain standards;
- prescription of radiation shielding in walls of the practice; and
- licensing of radiologists who run practices.

A voluntary accreditation scheme for medical imaging practices is jointly administered by the Royal Australian and New Zealand College of Radiologists (RANZCR) and NATA.

In June 2003, the Government, the Royal Australian and New Zealand College of Radiologists (RANZCR) and the Australian Diagnostic Imaging Association (ADIA) entered into the current MoU, which provides capped funding of $5.7 billion over five years for radiology services covered by Medicare.

The implementation of successive MoUs by the Government contributed to a process of industry consolidation. Many small-medium operators consolidated to form large entities. However, there remain a raft of smaller operators which tend to operate as regional monopolists in small geographic areas.

As in Pathology services, there is no apparent correlation between the quality of services delivered and the level funding provided as specified in the MoU. Rather service quality is driven by:

- the system of tertiary referral which promotes continuous improvement in professional standards;
- strong non-price competition between operators on the basis of speed and accuracy; and
- ongoing development in technology. The industry must continuously invest in new technology as this demanded by both patients and radiology staff alike.

However, the current MOU does outline the development of a mandatory accreditation scheme with links to Medicare benefits as a priority. The Government is still considering the introduction of such a scheme, despite the November 2005 target date included in the MOU.

In May 2006, the Government responded to a legislative review, the 2004 Review of Enforcement and Offence Provisions in the Health Insurance Act 1973 as they relate to the provision of pathology services under Medicare, which had implications for Radiology. The Review made a number of recommendations that are potentially relevant to radiology and diagnostic imaging, being to expressly include statements of objectives which:

- prevent the splitting of Medicare benefits between requesters and providers;
- prevent requesting practitioners and their associates from receiving any financial benefit for sending requests to a service provider; and
- encouraging competition between radiology service providers on the basis of quality of service provided and cost to patients.

Many of the prohibited radiology practice provisions mirror those outlined in the pathology provisions. Consequently, the Government is proposing that they be amended at the same time as the pathology amendments. It is believed that addressing the issues in parallel will ensure that requesters and providers of pathology and radiology services are treated equally in respect of the proposed legislative changes.

6.3.2 Licensing of the pharmacy industry

Pharmacy involves the dispensing of medicines, through community and hospital pharmacies. Community pharmacies are highly regulated retail outlets, where medicines are stored and dispensed by pharmacists.

The States / Territories and the Commonwealth have all enacted legislation that regulates the pharmacy industry. The States' / Territories' regulations govern the:

- licensing requirements for pharmacists and pharmacy premises – covering educational qualifications and experience and premises standards;
- regulation of pharmacy ownership. – in most jurisdictions, the provisions generally limit ownership to qualified pharmacists (and thereby largely preclude corporate ownership by non-pharmacists) and limit the number of pharmacies owned; and
- controls on poisons (and medicines) distribution.

The Australian Government provides for regulations relating to the Pharmaceutical Benefit Scheme (PBS). These include provisions that:

- set pharmacists' dispensing fees;
- prohibit the discounting of consumer contributions for subsidised PBS drugs;
- control the location of pharmacies approved to dispense PBS drugs; and
- provide additional payments to pharmacies in isolated and remote locations.

The remuneration for pharmacists dispensing PBS medicines is set via five-year 'Community Pharmacy Agreements' between the Australian Government and the Pharmacy Guild of Australia. The agreement sets outs payments for the:

- cost of the medicine;
- delivery costs from the wholesaler to the pharmacy;
- retail mark-up to cover handling and storage costs; and
- dispensing fee for a pharmacist's professional advice and services.

Under regulatory legislation, ownership of pharmacies is limited to pharmacists who in turn are only allowed to own a limited number of pharmacies. Much of the income earned by the pharmacies is derived from government-funded remuneration and the fixed retail prices of products dispensed under the PBS. In addition, there exist a number of restrictions as on the location of dispensing pharmacies.

The major barriers to entry are centred on the high level of regulation surrounding the sector, in particular the ownership laws which limit the ownership of pharmacies to registered pharmacists.

It is important to recognise, however, that these ownership restrictions have also prevented the growth of major players or chains capable of dominating the market, which in many cases, can prove to be a substantial barrier.

6.4 Conclusions

The analysis presented in this chapter suggests that licensing and/or accreditation have potential to be an effective means of regulating ACCs to meet the objectives set out in section 5.2. However in developing the regulatory regime it will be important to ensure that it is implemented in a manner that seeks to minimise market failures while also minimising administrative and economic costs associated with the regime.

7 Operational restrictions

Within the broad ACC licensing framework there are a number of more specific competitive restrictions. These specifically relate to:

- eligibility to apply for a licence to operate a collection centre;
- standards of operation, equipment and personnel;
- the number of collection centres; and
- prices.

7.1 Approaches to regulation

There are generally two approaches to regulation: performance based regulation and prescriptive regulation. While prescriptive regulation specifies processes, techniques or inputs that must be used by providers, performance based regulations focuses on the outcomes to be achieved through regulation. Despite the fact that prescriptive regulation provides greater certainty, the relative advantage of performance based regulation is that it sets standards that must be reached but gives providers the freedom to choose how they will achieve those standards. In doing so it generally minimises or avoids the increased costs of compliance and reduction in scope for innovation generally associated with prescriptive regulation.

7.2 Restrictions on eligibility

Clause 5 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* places explicit restrictions on who can apply to operate a collection centre. Specifically application is limited to APAs who:

- operate and are the sole owner of an accredited category G laboratory (sub-cl.2(a));
- entered into an arrangement with another APA for the use of an accredited category G laboratory, providing that prior to the introduction of the ACC arrangements the APA did not operate a collection centre on the hospital premises of a recognised hospital and it was in an area designated as Rural and Remote (sub-cl.2(b));
- operate and are the sole owner of an accredited category S laboratory and prior to the introduction of the ACC arrangements was the holder of a unit of entitlement to operates a licensed collection centre (sub-cl.2(c)); and
- operate and are the sole owner of an accredited category S laboratory with the collection centre being located on the same premises, provided the laboratory received accreditation after the commencement of the ACC arrangements (sub-cl.2(d)).

The problems with these arrangements, from a competition perspective, is that they:

- prohibit certain market participants from operating collection centres (eg, Category B & M laboratories); and

- Create different rules for market participants depending on the time at which they were in operation (eg, Category S laboratories).

7.2.1 Application restrictions

Under clause 5 category B and M laboratories are also not permitted to apply for collection centre licences. Although there are specific grandfathering provisions associated with Category S laboratories, they are generally prohibited from applying for more than one collection centre which must be located at the laboratory.

Despite research and stakeholder consultation KPMG could not establish a clear rationale for restricting who may apply for licences for collection centres. During discussions with stakeholders there was some indication that these requirements may have been introduced in response to concerns over the quality of specimen collection.[53] However, as outlined in section 4.1.3, the acceptance and continuation of an undertaking of an APA and APP is affected by, amongst other things, whether or not the pathology authority holds accreditation through the NATA accreditation scheme for the category of services to be provided through the pathology laboratory. As noted in the Phillips Fox review:

> The link between NATA/accreditation and the acceptance and/or continuation in force of the undertaking is the main mechanism under the *HIA* regime for ensuring the quality of services that are supported by Medicare benefits.[54]

Given that APLs are required to gain NATA accreditation for the category of laboratory operated, the added benefits of limiting ACC eligibility due to quality concerns is questionable. KPMG is however concerned over the costs of the above limits on eligibility which are likely to include:

- Reductions in flexibility (i.e. limit the ability of providers to respond to market signals) – for example, under the current restrictions a Category S is only allowed to apply for one collection centre licence (which must be co-located at the laboratory). Should, in the future, the market change, as a result the laboratory is able to identify opportunities in the market, they may be unable to respond to consumer demand. This is likely to have implications for patient health and cost of service provision.

- Stifling innovation – are a disincentive for providers (particularly operators of Category B, S and M laboratories) to think of new and improved ways of doing things since they know that they are ineligible for certain activities.

- Limiting the profession's ability to gain economies of scale and scope – given the capital intensive nature of laboratories, increasing throughput is required to gain economics of scale

[53] The requirement to be an APA to hold a collection centre licence was introduced as part of the LCC reforms.
[54] Phillips Fox, 2005, *Review of Enforcement and Offence Provisions of the Health Insurance Act 1973 as they Relate to the Provision of Pathology Services Under Medicare: Final Report to the Department of Health and Ageing,* p.19.

and scope and hence reduce the average cost of supply. Ineligibility for collection centres reduces the chances of providers being able to access the required level of throughput.

Provided sufficient quality controls are in place KPMG believes that the costs associated with the above limiting eligibility for collection centre allocations to Category G laboratories do not outweigh the benefits of removing the restrictions, and as such should be removed.

Recommendation One - KPMG recommends that all types of laboratories be eligible for collection centres, subject to being owned by an APA.

7.2.2 Grandfathering provisions

'Grandfathering' is a process by which an initial allocation of licences or permits is based on historic use. Grandfathering clauses are often used in the reform process to ensure that reforms do not unfairly affect the existing arrangements, accrued entitlement and long-term planning of existing industry participants. Grandfathering is most commonly used with environmental and natural resource licensing reforms.

Clause 5 effectively contains two grandfather clauses. That is, APAs:

- are entitled to operate collection centres in respect of Category S laboratories if they were in operation prior to the introduction of the ACC arrangements;[55] and

- are entitled to operate collection centres operated in rural/remote areas through an arrangement with another APA to use its Category G laboratory provided that they were in operation prior to the introduction of the ACC arrangements.[56]

As KPMG has recommended that the eligibility restrictions be removed, subject to appropriate quality controls, grandfathering arrangements outlined above should also cease.

7.3 Restrictions on the standards of operation

7.3.1 Standards of operation

Clause 4 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* requires an application for an eligible collection centre to have on premises the necessary equipment and appropriate staff for the collection and preparation of specimens for pathology procedures.

As outlined in section 4.1.5.2 the NPAAC *Standards for Pathology Laboratories* explicitly state that the "collection of specimens should be performed in appropriate facilities and under

[55] These arrangements were introduced as a component of the eligibility reforms for Category S introduced on 26 November 2001 by amending the *Health Insurance (Eligible Collection Centres) Approval Principles 2001.*
[56] Introduced as an amendment to the Health Insurance (Eligible Collection Centres) Approval Principles 2001 on 8 October 2001 to ensure that access to rural and remote areas were not lost.

appropriate conditions" while the NPAAC *Guidelines for Approved Pathology Collection Centres 2006* lists the minimum requirements to apply to collection centres.

Given that laboratories are also required to apply for NATA accreditation to be eligible for Medicare benefits, stakeholders were confident that the current accreditation process for ACCs is providing high quality pathology services as well as consistency in quality throughout the pre-analytical, analytical and post-analytical phases. In addition, as noted by the AAPP, NPAAC standards and the NATA accreditation process is only one component of a range of quality assurance measures for pathology providers:

> Pathology is in the vanguard of quality assurance through measures such as:
>
> - Regulation – of pathologists, of pathology companies and of pathology laboratories;
> - Standards development through the National Pathology Accreditation Advisory Council;
> - Assessment and accreditation of pathology laboratories by NATA/RCPA Peer Review system; and
> - Quality Assurance Programs:
>   - externally through the Royal College of Pathologists of Australasia - QAP Pty Ltd'; and
>   - other systems providing internal QAP programs.[57]

During consultation a number of stakeholders emphasised that the current system of collection centre accreditation was working well in ensuring quality of specimen collection and that there was no need for an additional layer of regulation in the form of licensing. They also stated that, if licensing was removed, they believed there would be no fall in the standard of collection centres.

During consultation however it was revealed that, as part of the laboratory assessment process, NATA will inspect one collection centre per laboratory and that in practice, it is usually the collection centre attached to the laboratory. Hence, unlike laboratories, not all collection centres are inspected or accredited.

Given that collection centres in rural and regional areas are generally some of the furthest away from the laboratories, and hence less likely to be inspected, some stakeholders were concerned about quality in these centres. Given that these centres often have lower throughput than there metropolitan counterparts, they are less likely to be profitable and hence face greater cost pressures. Without sufficient quality controls, there is a risk that a firm subject to price regulation will reduce quality in its endeavours to maximise profits. Some stakeholders confirmed these concerns with comments such as "there are collection centres out there that do not meet the standards".

Comments of this nature are concerning because any potential fall in the quality of collection centres has the potential to impact on the quality of the overall testing and reporting process, and hence the health outcomes for the consumer and the economy more broadly. Importantly, lower quality health outcomes lead to increases in the costs of health service over the medium to longer term.

[57] AAPP, *Impact of Advances in Medical Technology on Healthcare Expenditure in Australia, Submission to the Productivity Commission*, 29 November 2004.

The current costs of accrediting collection centres is built into the laboratory accreditation costs as they are undertaken as part of the laboratory accreditation process.

Discussions with stakeholders have indicated that full accreditation would cost around $1,000 per centre, the approximate cost of the licence tax. However if required, in addition to the licensing component, this would significantly increase the cost of compliance (particularly for small providers) and lead to further cost pressures on the MoU.

Given the high risk nature of quality of pathology services, KPMG believes that there is a need to strengthen the quality control provisions of *Health Insurance (Eligible Collection Centres) Approval Principles 2005*. However, given the overall costs of licensing and accreditation (eg, APAs, APPs, APLs and ACCs), the regulations need to enable providers sufficient flexibility to meet the specific requirements at the lowest cost possible to the individual provider. It is also important that the cost of compliance does not reach a level that creates further barriers to entry.

Recommendation Two - KPMG recommends that clause 4 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* be amended to specify that appropriate quality standards must be met.

Recommendation Three - KPMG recommends that all collection centres be subject to more uniform and greater quality control mechanisms.

7.4 Restrictions on the number of ACCs for new entrants

The *Health Insurance (Eligible Collection Centres) Approval Principles 2005* places restrictions on the number of collection centres an APA can operate. Specifically if an accredited G laboratory has been in operation:

- for at least two full consecutive calendar years the maximum number of approvals that may be granted is determined by dividing the number of patient episodes (for which the APA provided a pathology service, or services, during the calendar year immediately preceding the calendar year in which the relevant financial year commences) by 14,200 (cl.11);

- for less than a full calendar year immediately preceding the calendar year in which the application is made – 2 (cl.12(2)(a));

- for a full calendar year in which the application for approval is made, but less than two full consecutive years – the higher of dividing the patient episodes by 14,200 or 2 (cl.12(2)(b));

Clause 11(3) and 12(4) also permits an additional collection centre to be operated in the same premises as the laboratory.

The above restrictions were identified by the majority of stakeholders as creating barriers to entry and being anti-competitive. However some providers disputed these claims stating that there were aware of several examples of new pathologists starting up new businesses.

It was also emphasised that when the ACC scheme was introduced, the transition arrangements allowed providers to maintain the same number of licences for three years which gave providers time to grow the number of patient episodes to maintain their previous allocation of licences. Given that some small to mid sized providers did not generate sufficient volume of patient episodes to maintain their previous number of licences, they lost licences after the 3-year transition period ended. It is also believed that there remains a number of non-viable ACCs.

There are essentially two, somewhat interrelated, components of these arrangements that require investigation. These include:

- the licence cap; and
- the quota system (including the use of a 'floor').

7.4.1 Licence restrictions

As outlined in section 4.1.5 restrictions on units of entitlements and hence licences, were introduced as part of the LCC arrangements. These restrictions aimed to reduce industry costs and hence the costs to Medicare and the community by limiting the number of collection centres allowed to operate.

While there is evidence to confirm reduction in the growth in Medicare funding, it appears that these reductions have predominantly been driven by the MoU with licence restrictions providing certainty in the market and helping to facilitate cost reductions and increases in efficiency.

Although the licensing regime has helped reduce costs and increase the efficiency of providers, there are a number of drawbacks with this approach. As previously illustrated licensing leads to losses in economic efficiency. There are also problems with ensuring appropriate access and, depending on the allocation method, ensuing that those who value the licences the most receive their desired allocation.

During stakeholder consultation a range of negative outcomes were highlighted. These included:

- Inadequate access to pathology collection services - while there are specific provisions aimed at improving access to rural and regional areas (these are discussed in section 7.4.4) stakeholders were concerned that there was insufficient access in some areas/regions not covered by the rural and regional provisions. With licences limited there was concern that licences would be relocated to areas of higher throughput and hence higher profits.
- Lost opportunities – a number of stakeholders have identified commercial opportunities but have emphasised that they have been unable to pursue them given the restrictions.

- The creation of a commercial value greatly exceeding the value of the physical assets involved[58]

When asked what the impact of removing the licence cap would be, a number of stakeholders indicated that it would result in "open slather', and a return to the situation where there was a collection centre 'on every street corner'.

KPMG does not concur with this view for a number of reasons. Firstly, although not an identical comparator, experience in the pharmacy and radiology industries have shown this not to be the case. Secondly, given the increasing corporatisation of the industry it is unlikely that, in the longer term, providers will continue to operate unprofitable collection centres. Hence, as emphasised the UK Deregulation Task Force, consumers, rather than authorities, should decided what premises are needed and where.[59]

A majority of those stakeholders consulted however, indicated that the preferred scenario would be to remove the licensing restrictions all together in order to provide a level playing field for all providers. While the main objective of removing the licence cap will be to increase competition, KPMG is mindful that, with the current high market concentration levels, any increase in competition could possibly manifest itself in further increases in concentration levels.

As illustrated in section 3.1.4, there has been a clear trend of increasing market concentration , particularly since 2001. Based on data provided by the Department, KPMG estimates that the largest four providers have increased their share of collection centres from 51.2 per cent to 77.9 per cent, noticeably above the market concentration thresholds identified by the ACCC. Hence, as identified by the ACCC there is a risk that these firms will use their market power to extract monopoly profits through price and non-price competition. Furthermore as previously identified, increasing levels of concentration elevates the risk of strategic actions and coordination of activities between market players.

7.4.2 The allocation factor

The allocation factor (ie, the patient episode benchmark) to earn a unit of entitlement is currently set at 14,200. This represents the ratio of MBS episode activity to allocated units of entitlement as at July 2001 and was calculated from MBS and Department of Veteran Affairs (DVA) episodes performed over the period 1 January 2000 to 31 December 2000 by date of service.[60]

At the time of calculation, it was reported that 14,200 episodes was considered to be an objective and measurable threshold based on episodes derived according to the legal definition of an episode as defined in the *Health Insurance Act 1973*.[61]

[58] This was also raised in the Report to the review of Commonwealth legislation for pathology arrangements under Medicare, Final Report, December 2002. KPMG reviewed the 2005 financial reports of Sonic Healthcare Limited, Mayne and Health Scope which revealed that theses companies carry significant amounts of intangible assets that relate to assets such as goodwill, intellectual property, patents, brand names, licences and operating rights.
[59] UK Deregulation Task Force, Deregulation Task Force Report 1994/95, London, 1995.
[60] Attachment A – Pathology Quality and Quality Outlays
[61] Attachment A – Pathology Quality and Quality Outlays

Many industry stakeholders expressed concerns that the current ACC scheme imposed asymmetrical limits to growth across pathology providers, enabling large players to benefit from organic industry growth but precluding the smaller players from sharing in this growth. This issue arises due to the formula's use of 14,200 episodes as the additional patient episode throughput required to operate another collection centre. While 14,200 episodes might be a small proportion of a large service provider's throughput, a small start-up provider granted two licences not only has to generate 14,200 patient episodes for each centre to keep them open after the two-year temporary floor, but they also have to grow as much as 25 per cent to gain an additional licence. This situation is illustrated below.

If annual growth rate in patient episodes is assumed to be around 7 per cent and the average throughput of each collection centre is 14,200 (which is subject to debate), then:

- A provider with 100 collection centres will have around 1,420,000 episodes per year. In a single year a 7 per cent growth rate will increase throughput by 99,400 episodes, enough to earn the provider an additional 7 centres.

- A provider with 4 collection centres will have around 56,800 episodes per year. In a single year a 7 per cent growth rate will increase throughput by only 3,976 episodes, not enough to earn an additional unit of entitlement. Hence the additional 10,224 episodes, or 18 per cent growth, in patient episodes required to earn an additional centre will need to be achieved through other means.

The above analysis is of course static. If the cumulative effects of the above are considered over a five year timeframe the provider with 100 will have increased units of entitlement to 139 at the end of the 5th year based solely on the natural growth in patient episodes while the smaller provider may have increased by between 0 and 1 units of entitlement.

The effects are of course magnified if based on lower average levels of episode throughput or if growth rates a greater than the 7 per cent used in this example.

This restriction also has a 'catch 22' nature, being that in order to grow, a pathology business needs to increase its number of collection centres to capture more patient episodes, however the regulations restrict the operation of more collection centres until the business can demonstrate an increase in its number of patient episodes. An example illustrating this is set out below.

KPMG reviewed the current use of the patient episode benchmark and has identified some inherent problems with the current approach. In particular:

- the number is static rather than dynamic and does not reflect the evolving nature of the market and the profession;

- the number is backward looking. That is the information underpinning the calculated unit of entitlement was based on activity data from 1 January 2000 to 31 December 2000;

- it is not an accurate reflection of the average throughput of a collection centre. Preliminary estimates indicated that the average throughput of a collection centre is in the vicinity of 6,000 patient episodes per year; and

- it inhibits the growth of smaller providers while facilitating the growth of larger providers, hence it creates an uneven playing field.

During consultation there were diverging views on the appropriateness of the patient episode benchmark and the suitability of other allocation methods. For example, some stakeholders emphasised that only the number of patient episodes collected at an ACC should be counted towards the target while others believed that all patient episodes should be included.

Over the course of the review it has become increasingly clear that the method for allocating licence entitlements is a contentious issue. It has historically been the subject of significant debate and careful consideration of the future mechanism is needed. For this reason a range of allocation options are considered in Chapter 8.

7.4.3 Licence floor

The *Health Insurance (Eligible Collection Centres) Approval Principles* provides for a temporary floor of two entitlements for the first two years of operation. After this period entitlements are based on the '14,200' rule.

During consultation small and medium providers continually emphasised that these provisions are a significant barrier to entry for new entrants because:

- two collection centres are significantly lower than what is required to operate an economically viable business – stakeholders identified that 10 collection centres were required to be economically viable and that 5 would be a breakeven point;

- two years is too short a time a develop sufficient throughput to compete on equal grounds with other more established providers; and

- given the capital intensive nature of laboratories there are significant start up costs requiring longer payback periods. As such potential entrants require a longer period of certainty to justify the business case for entry.

Over the course of the review KPMG found it difficult to pinpoint exactly how the number '2' was determined, or the justification for it. Following discussions with a number of small providers who were at various stages of operation as well as those considering establishing laboratories, KPMG agrees that the current provisions create significant barriers to entry and should be reviewed.

In addition to the exact number of the floor there was significant discussion surrounding whether the floor should be temporary or permanent. While there may be a need to introduce some form of mechanism to create a more level playing field for small and medium providers, KPMG is mindful that permanent floors do not encourage efficiency improvements through

diversification and innovation. Rather, they may be used as a form of "safety net" which in fact may place them at a competitive advantage over their larger counterparts.

Given that pathology providers essentially compete on quality of service grounds, as opposed to traditional price competition, care also needs to be taken that, in moving to the new arrangements, smaller providers are provided with sufficient time and opportunity to respond to a more even playing field. Therefore, given there is justification for providing new entrants with a temporary floor, we turn to the issue of how to determine the appropriate period of effect.

KPMG investigated the effective lives of depreciable assets under the Australian income tax laws. Specifically, Taxation Ruling 2000/18 (TR 2000/18) determines the effective life of assets in health and community services (among other industries) and provides an effective life for a blood count machine of five years. Accordingly KPMG proposes a temporary floor of five years would provide new entrants the opportunity to operate for a length of time equivalent to the period of initial investment in this type of equipment.

KPMG considers seven licences is reasonable magnitude for the temporary floor. This is based on the midpoint between the number of collection centres required to breakeven on initial investments and the optimal number of collection centres for a start up business, as indicated to KPMG by stakeholders.

Recommendation Four - KPMG recommends that, should licences continue to be restricted, a temporary floor of seven be introduced. The licence floor should remain in place for five years.

7.4.4 Collection centres in rural and remote areas

Clause 10 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* permits the holder of a unit of entitlement in certain specified rural and remote areas to cover three licences.

This provision was introduced as part of the LCC scheme to give APAs a commercial incentive to locate specimen collection centres in rural and remote areas and thus promote access for rural and remote Australians to pathology specimen collection services.

While the objective of this provision is clearly to enhance access to pathology collection services in rural and remote areas, there appears to be significant confusion regarding the operation of the scheme, in particular the eligibility. For example, when questioned about the basis of the scheme stakeholders referred to:

- the RRMA (Rural, Remote and Metropolitan Areas) classification;
- the ARIA (Accessibility/Remoteness Index of Australia) classification; and

- ASGC (Australian Standard Geographical Classification) Remoteness Areas.[62]

Research has indicated that the designated areas are based on the Australian Bureau of Statistics (ABS) Australian Standard Geographic Classification (ASGC) and are defined as 'Rural Other' and 'Remote Other' as set out in the Rural and Remote Areas Classification published by the Department of Human Services and Health. This scheme was developed to provide a basis for assessment of:

- problems of providing services in particular areas;
- services and needs in disadvantaged areas; and
- access and equity considerations.[63]

While some stakeholders believed that the current system is an effective means of providing access to pathology collection centres in rural and remote areas, other stakeholders believed that access remained a key issue for the current licensing arrangements. Of concern are the reports that the 3:1 provisions are being used in what are now generally considered Outer Metropolitan Areas.

While unlikely to have been the intention of the scheme, it is likely that the needs and characteristics of many regions previously identified as rural and remote (based on 1991 SLA boundaries), have changed over the past 15 years. A simple analysis of the 'Rural Other' and 'Remote Other' SLAs in Queensland has indicated that this is likely to be the case.[64]

This problem is not unique to Rural/Remote Areas Classification, with other schemes such as RRMA and ARIA subject to similar shortcomings.[65] KPMG notes that the Department of Health and Ageing is currently undertaking a comprehensive review of the RRMA scheme, which is a remoteness classification also based on 1991 population Census data and 1991 Statistical Local Area Boundaries (SLA) boundaries.[66] In particular the review emphasises that:

> … RRMA's applicability to health related programs is also limited because it does not take into account important specific factors such as the workforce level or **the health needs of a region** [emphasis added].

The Department has identified that geography, workforce supply and health and wellbeing are key factors that influence levels of access, and as a result are aiming to develop a flexible national classification system that takes into account the characteristics of individual regions

[62] Further information on these classification systems can be obtained in Australian Institute of Health and Welfare Classification System, *Rural, Regional and Remote Health*: A guide to remote classifications, Canberra, August 2004.
[63] Department of Human Services and Health, *Rural/Remote Areas Classification*, Canberra, January 1994.
[64] For example, 'Rural Other' covers areas such as Caboolture (S) – Pt B, Caloundra (C) – Pt B, Maroochy (S) – Pt B, Noosa (S) – Pt B.
[65] For example as urban centres expand, areas that are considered rural or remote for RRMA purposes may no longer actually be rural or remote because their proximity to an urban centre has changed or because those areas themselves have also expanded. Conversely, other areas that have had population decreases may have become more isolated than their RRMA classification indicates.
[66] See http://www.health.gov.au/internet/wcms/publishing.nsf/Content/pcd-pub-rrmareview.htm.

and their access to health services, to facilitate targeted support to the areas that need it most. At this stage there is no set timeframe for the completion of the RRMA review.[67]

Given that the Government's *Rural Health Strategy* aims to improve health outcomes for rural and remote Australian by, amongst other things, increasing health services to regional, rural and remote Australia,[68] KPMG considers that specific incentives for increasing access to pathology collection centres in rural and remote areas are appropriate. However, for reasons noted above, KPMG is concerned that the 'Rural/Remote Areas Classification' does not fully achieve the stated objectives.

One option is to provide community service obligation payments to encourage service providers into rural / remote areas. However, KPMG acknowledges this form of incentive would impose a significantly higher administrative burden on the Department, which may be above and beyond the objectives of the scheme.

At a high level, the current rural / remote scheme appears to successfully entice pathology service providers into those areas classified as rural remote. We consider the main concerns with this scheme relate to the outdated classification system rather than its overarching concept. Given the population profiles of Australian regions have undoubtedly changed since the 1991 census, the rural / remote incentives for the pathology industry should match in context the outcomes of the RRMA review. However this will require a structured concordance process to educate stakeholders of changes in classifications.

Recommendation Five - The method of providing access to pathology collection centres in rural and remote areas should be reviewed in light of the outcomes of the RRMA review. Should restrictions on licences be removed, consideration could be given to introducing other policy mechanisms aimed at ensuring access to pathology collection centres in rural and regional areas.

7.4.5 Grandfathering provisions

Clauses 13 and 14 of the Health *Insurance (Eligible Collection Centres) Approval Principles* contain grandfathering clauses which provide immunity from the new arrangements. They have the effective of allowing the following parties to continue operating the number of collection centres they were operating immediately prior to the introduction of the new arrangements:

- collection centres operated in rural/remote areas through an arrangement with another APA to use its Category G laboratory provided that the collection centres were not located on the hospital premises of a recognised hospital (cl.13); and

- operators and sole owners of accredited category S laboratories (cl.14).[69]

[67] Correspondence with the GP section of the Department of Health and Ageing.
[68] See http://www.health.gov.au/internet/wcms/publishing.nsf/Content/ruralhealth-policy-budget.htm.
[69] There were 11 Category S laboratories in this situation.

KPMG understands that clause 13 was introduced in response to concerns of loss access in rural areas:

> "…the existing community based collection centre facilities in rural and remote areas would be grandfathered to ensure that access to established collection centre services by these communities was not lost."[70]

As previously outlined, clause 10 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* contains specific provisions aimed at increasing access to pathology collection services in rural and remote areas. Despite some concerns over the current scheme's ability to facilitate access in rural and remote areas KPMG considers that there is a significant degree of overlap between clauses 10 and 13.

In addition, given that KPMG has recommended that clause 4 be amended so that eligibility is based on meeting appropriate quality standards, rather than based on ownership or laboratory category, this will make both clauses 13 and 14 redundant.

7.5 Limitations on price

Section 4A of the *Health Insurance Act 1973* states:

(1) The regulations may prescribe a table of pathology services table that sets out the following:

(a) items of pathology services;

(b) the amount of fees applicable in respect of each item;

(c) rules for interpretation of the table.

The table, including lists of the items of pathology services and the amount of fees applicable for each item is set out in the *Health Insurance (Pathology Services Table) Regulations 2005.*

As outlined in section 4.2.1.1 the PST sets the rebate levels for approved pathology services. That is, it regulates the funding provided by the government for undertaking pathology testing, it does not restrict the amount that can be charged for a test.

For providers that choose to bulk bill, the Medicare rebate is their sole source of funding (because patients do not incur any out of pocket expenses). However, providers that do not bulk bill have two choices: they can privately bill the patient at a level that includes a gap payment (the difference between the Medicare rebate and the charge for the episode) or accept the Medicare rebate as payment themselves. The decision of whether to bill or accept the Medicare rebate is essentially an organisational decision and to some extent a competitive market decision.

It is important to note that these provision do not restrict providers from providing different services (eg, non-Medicare funded pathology tests) or above the Medicare rebate for the tests.

[70] Changes to Health Insurance (Eligible Collection Centres) Approval Principles since 1 December 2001.

7.6 Licence taxes

Under section 23DNBA(2) of the HIA an approval for an eligible collection centre will not be granted until the tax on the grant has been paid.[71] The tax, is currently set at $1,000 per annum (pro rata for part thereof) and paid to Medicare Australia at the time of application.

In addition to this tax there are a range of fees levied on the pathology industry. The following table sets out the licence fees and taxes for APAs, APPs, APLs and ACCs.

Table 7: Licence fees/taxes for pathology providers

Entity	Approx No	Fee/tax amount	Payment period
APA	156	$1,500	Annually
APP	791	$500	Annually
APL Category GX Category GY Category B Category M Category S	550 87 116 244 17 86	 $2,500 $2,000 $1,500 $750 $750	3 yearly
ACC	1974	$1,000	Annually

In addition to the licensing tax/fee there are costs associated with Quality Assurance (proficiency testing) and NATA inspection of laboratories (see Table 3).

A few stakeholders considered that the licence fee structure was inappropriate and excessive and created barriers to entry, particularly for small providers and general practitioners. This claim is not uncommon, with it generally recognised that licensing fees have a relatively greater incidence on small firms.[72]Some stakeholders also claimed that there was not justification for the current licence fees and they believed they were arbitrarily set.

An efficient licensing fee structure should be levied on a cost reflective basis. That is, licensed should be set to cover the cost of administration and enforcement. As such, both the roles of the Medicare Australia, which is responsible for the administration of the ACC scheme,[73] and the Department of Health and Ageing, which is responsible for advising on the policy aspects of the scheme, should be considered in any cost analysis.

Based on the fee amounts and number of licences held KPMG has estimates that the licence fees/tax paid by the pathology profession in 2005 to the federal government was just under $3.5

[71] Tax on the grant of an approval is imposed by the *Health Insurance (Approved Pathology Specimen Collection Centres) Tax Act 2000*.
[72] Bureau of Industry Economics, *Business licensing – International Benchmarks, Report 96/9*, AGPS, Canberra, June 1996, p xxi.
[73] The administration role of the HIC includes the application of the principles of determination, allocation of units of entitlement, issuing of licenses and collection of license fees, and the detection of inappropriate practice and fraud in relation to collection centres and their operations.

million, of which nearly $2,000,000 was in the form of a tax (which is paid directly into consolidated revenue).

Recommendation Six - Fees for licences should be reviewed so that, in addition to being based on cost recovery principles, they do not unnecessarily create barriers to entry for small firms or individuals.

7.7 Licence trading

During the course of the review discussions with stakeholders revealed that the trading of licences was occurring due to the restrictions identified above. While a clear majority of stakeholders emphasised that this **was not the intention** of the scheme, there are currently no regulatory provisions that restrict the trade in licences.

As previously discussed the current restrictions have had the undesired effect of increasing the value of the licence to a point beyond the value of the physical assets involved (ie, there is an intangible value attached to a licence allocation). Given the value of the licences and the fact that there are a large number of unused licences (eg, more than 200) a market has emerged.

KPMG has received evidence that some providers are selling their unused licences to other providers wishing to establish more collection centres beyond their allocation. While the values remain confidential, KPMG can reveal that they are not negligible. Depending on the type of laboratory operated and the time at which operations commenced, some pathology providers have been able to sell their licences each year, only to see them returned at the time of reallocation, so that they can sell them again the following year. It is alleged that these providers have built the revenue from licence sales into their annual business models.

During consultation stakeholders conveyed varying views at the ability of providers to trade licences, ranging from outrage to absurdity. However, Medicare Australia has confirmed the legality of licence trading.

It is important to note that one of the key advantages of licence trading is that, with restrictions on access limited, trading allows those providers who value the licence the most to access it. Any prohibition on trading is in fact a restriction to competition and, in light of this NCP review, must be clearly justified in terms of its objectives.

7.8 Conclusions

This chapter has reviewed the competitive operational restrictions within the broad ACC licensing framework. Given the current regulatory requirements along the service continuum (as discussed in Chapter 4 and summarised in section 4.3) KPMG recommends that future regulatory arrangements for ACCs be based on the following:

- a licensing regime with eligibility based on:
    - status as an APA; and

  - meeting appropriate quality standards;

- specific targeted and transparent provisions to facilitate regional and rural access;
- if licence restrictions are maintained, a temporary floor of seven licences for five years; and
- licence fees (not taxes) set on a cost-reflective basis.

As previously discussed Chapter 8 contains an in depth analysis of the licence allocation factor, the final component of the ACC arrangements.

8 Reform options

This chapter considers a number of options for reforming the allocation of collection centre licences. These options, which were highlighted by stakeholders over the course of the review, are:

- Option One – no allocation of licences;
- Option Two – current allocation method;
- Option Three – allocation based on growth in all patient episodes;
- Option Four – allocation based on average throughput of ACC applied to ACC patient episodes only;
- Option Five – allocation based on average ACC throughput applied to all patient episodes; and
- Option Six – allocation based on average throughput of ACC on recognised regional basis.

While the NCP legislative review process generally requires an assessment of the status quo, it has not been evaluated as a future option for allocating collection centre licences because of the reasons previously discussed throughout Chapter 7. However Option 2 is a 'modified status quo' which considers the current allocation method with an increased temporary floor.

The expected impacts of each option is discussed in the following sections.

8.1 Option One – No allocation method

Under Option One there is no limit placed on licences (except for the general eligibility criteria outlined in section 7.8) and as a result no allocation method is required. As there is no method of allocation, this effectively negates the provisions associated with the licence floor and the 3 for 1 provisions aimed at increasing rural and remote access. Nevertheless, KPMG notes that (as discussed in section 7.4.4), there may be a range of other policy measures available to facilitate access to pathology collection centres in rural and remote areas.

Table 8 illustrates the likely benefits and costs of this option to a range of pathology stakeholders.

Table 8: Likely impacts of Option One – No allocation method

Key stakeholder groups	Benefits	Costs
Small provider	Increases the scope for competition and ability to respond to the market. Licences provided to those that seek them. Provides opportunities to increase episode throughput to gain economies of scale. Creates even playing field.	Increases the short run cost of serve. Removes temporary licence entitlement floor. Reduces value of existing licences.
Medium provider	Increases the scope for competition and ability to respond to the market. Licences provided to those that seek them. Provides opportunities to increase episode throughput to gain economies of scale. Creates even playing field.	Increases the short run cost of serve. Reduces value of existing licences.
Large provider	Licences provided to those that seek them.	Increases the short run cost of serve. Removes mechanisms facilitating growth of market share. Reduces value of existing licences.
Government	Reduces administration costs.	Likely to increase pressure on the MOU as providers increase collection centres (i.e. because of rising costs).
Consumers	Increases access and choice.	

8.1.1 Benefits of Option One

Option One would encourage competition by lifting the limit on collection centre numbers, thus enabling both small and large providers to place collection centres wherever they perceive to be commercially viable. As a result collection centre numbers should increase, resulting in increased access and choice for consumers, and thus leading to improved health outcomes for the broader community.

Removing the collection centre restrictions should also reduce the cost of administration and policy development which should flow through to lower licence fees for ACCs.

8.1.2 Costs of Option One

KPMG recognises stakeholder concerns that a major consequence of lifting restrictions will be rapid growth in collection centre numbers, at least in the short term. In the short run, this may

increase the costs of serve and is likely that the profession may use this scenario as a reason to increase pressure on the MoU. As emphasised by one stakeholder:

> "Opening up competition would increase pressure on the MOU. The industry would see the removal of licensing as a supply-side restrictor as evidence that the Government is not supporting the cap and would abandon the MOU."

While KPMG acknowledges that this is likely to be the profession's immediate response to removing the licence restrictions, it is likely that in the medium to longer term the number of collection centres will reduce to a more sustainable level. As previously discussed the placement of collection centres is a business decision, and those collection centres which are commercially unviable (i.e. for which the patient episode throughput is too low to generate sufficient revenue to justify its existence) will cease to operate.

In creating a more even playing field, this option removes the mechanism which is facilitating the growth in ACCs held by large providers. While this will open up the market for smaller providers, it will also abolish the temporary floor offered as a component of a method of allocation, and hence any protection. We note the ultimate effect of opening the market in this manner could be either an increase in competition or further industry consolidation.

8.2 Option Two – Current allocation method

As detailed in section 7.4.2 the number of collection centres operated is currently restricted depending on the APA's patient episode throughput (using the '14,200' formula). However under this option, new entrants will receive an increased floor in the form of a five year temporary allocation of seven licences.

Table 9 illustrates the likely benefits and costs of this option to a range of pathology stakeholders.

Table 9: Likely impacts of Option Two – Current allocation method

Key stakeholder groups	Benefits	Costs
Small provider	Provides flexibility for locating ACCs. Preserves intangible value of licences.	Impedes growth (i.e. requires around 70 patient episodes per day to earn a new licence). Impedes the achievement of economies of scale.
Medium provider	Provides flexibility for locating ACCs. Preserves intangible value of licences.	Impedes growth (ie, requires around 70 patient episodes per day to earn a new licence). Impedes the achievement of economies of scale.
Large provider	Protects and enhances market share. Facilitates achievement of economies of scale and scope required to maintain MoU. Provides flexibility for locating ACCs. Preserves intangible value of licences.	Increases licences of small providers and new entrants and potentially increases competition.
Government		Relatively higher administration costs.
Consumers	Increases access to ACCs in line with pathology growth (although possibly not uniformly).	Does not require all allocated licences to be utilised. Limits consumer choice.

8.2.1 Benefits of Option Two

The current allocation method provides for ACC growth in line with pathology episode growth and allows APAs to be flexible with respect to the location of their ACCs. However this may mean growth in ACCs is not uniform geographically, potentially limiting access and service provider choice for consumers.

8.2.2 Costs of Option Two

As discussed in section 7.4.2, the assumption that an increase of 14,200 patient episodes should equate to an additional licence imposes asymmetrical limits to growth across pathology providers. This is because 14,200 episodes represents a relatively lower growth rate for a large provider than a small provider. Accordingly, large players benefit from additional licences received as a result of organic industry growth, while small providers receive limited (if any) additional licences and therefore remain stagnant.

While the current arrangements may assist economies of scale in larger providers and thus foster efficiency in service provision, it impedes the growth of smaller providers and thus the achievement of their own economies of scale. However at current industry concentration thresholds, the scope for further efficiency gains from this source may be limited. Furthermore, concerns have been raised about the potential for unilateral market power or coordination of activity between the large service providers.

8.3 Option Three – Allocation based on percentage growth in all patient episodes

Given that KPMG has identified that the current '14,200' formula creates an uneven playing field between the small and medium providers and large providers, it was suggested that licence allocations be based on growth rates in patient episodes rather than a fixed number.

The outcome, a percentage growth rate of 9.9 per cent was calculated using the following approach:

- The growth rate for each APA to gain an additional licence between 2004 and 2005 under the '14,200' rule was calculated; and

- An average of these growth rates was calculated, weighted according to the number of collection centres held by the APA.

As the required rate to gain an additional licence under the 14,200 formula currently ranges between 30,869 per cent for the smallest APA (46 patient episodes) to 0.1 per cent for the largest (9,691,694 patient episodes), the required growth in patient episodes also varies, from 5 patient episodes (over the year) to 960,000 patient episodes.

Based on current activity levels, the number of licences would be expected to increase by 454, excluding new entrants.

Table 10: Likely impacts of Option Three – Allocation based on percentage growth in all patient episodes

Key stakeholder groups	Benefits	Costs
Small provider	Reduces current barriers to growth. Increases licence entitlements. Increases scope for competition and ability to respond to the market.	Reduces intangible value of licences.
Medium provider	Reduces current barriers to growth. Increases licence entitlements. Increases scope for competition and ability to respond to the market.	Reduces intangible value of licences.
Large provider		Creates barriers to gaining additional licences and subsequently decreases licence entitlements. Increases licences of small providers and new entrants and potentially increases competition. Will reduce market share. Reduces intangible value of licences
Government		Will result in substantial increase in pressure on the MoU as growth rate in patient episodes exceeds allowable growth rate under the MoU. Relatively higher administration costs.
Consumers	Likely to increase access and choice	All allocated licences may not be used.

8.3.1 Benefits of Option Three

A major benefit of this option is that it reduces the barriers to growth currently facing small and medium providers by creating a uniform target growth rate for all providers. This is likely to increase competition in the market and lead to increased access and choice for customers.

8.3.2 Costs of Option Three

As outlined above the required percentage growth rate is based on the '14,200' rule which, as previously emphasised, establishes asymmetrical limits to growth across pathology providers. The conversion of this figure into a growth rate also creates asymmetrical limits to growth, but has the reverse effect. That is, the growth in patient episodes required by one of largest providers has been calculated to be in the order 960,000, while the smallest only needs to

generate an additional five patient episodes. When the cumulative effects of this option over time is considered, the benchmark for large providers increases significantly.

In addition, as the required growth rate exceeds the allowed growth in costs under the MoU, this option will significantly increase the pressure on the MoU.

8.4 Option Four – Allocation based on average throughput of ACC applied to ACC patient episodes only

Option Four replaces the '14,200' formula with a formula based on the average ACC throughput (i.e. 6,000 patient episodes per year[74]). However the key difference is that this allocation formula is applied only to patient episodes initiated in an ACC.

Table 11 illustrates the likely benefits and costs of this option to a range of pathology stakeholders.

Table 11: Likely impacts of Option Four – Allocation based on average throughput of ACC applied to ACC patient episodes only

Key stakeholder groups	Benefits	Costs
Small provider	Increases licence entitlements. Preserves and potentially increases intangible value of licences.	Removes automatic allocation for non-ACC patient episodes. Creates barriers to entry and diversification. Will increase market concentration and potentially decrease competition.
Medium provider	Increases licence entitlements. Preserves and potentially increases intangible value of licences.	Removes automatic allocation for non-ACC patient episodes. Creates barriers to entry and diversification. Will increase market concentration and potentially decrease competition.
Large provider	Will increase market concentration Preserves and potentially increases intangible value of licences.	Removes automatic allocation for non-ACC patient episodes.
Government	Relatively lower cost pressures on the MoU.	
Consumers	Reduces number of unused licences. Increases consumer access and choice.	

[74] Based on Medicare Australia data 2005 and KPMG estimates.

8.4.1 Benefits of Option Four

As a large number of unused licences are allocated to providers based on their non-ACC patient episode activity, a major advantage of this approach is that the number of unused licences are expected to fall.[75] Hence there is likely to be greater utilisation of existing licences and greater consumer access.

At the same time the overall number of licences is expected to remain around the same as the current number. This is likely to place relatively lower cost pressures on the MoU compared to other options.

8.4.2 Costs of Option Four

The main concern with this option is that it creates barriers to entry both to new providers and existing providers wishing to diversify. For example under this option, established service providers that do not operate collection centres (e.g. histology laboratories) but wish to expand into other pathology disciplines would not hold any licence entitlements. This is because they would have not registered any previous collection centre activity, and because not technically "new entrants" they would be ineligible for the licence floor.

Further, as this option removes hospital based patient episodes from the equation, the allocations currently given to hospitals (mostly of which are medium-sized providers) will be reallocated across existing ACC providers. The reallocation of licences is expected to lead to increases in market concentration levels, with the resulting effect of decreasing competition.

8.5 Option Five - Allocation based on average ACC throughput and applied to all patient episodes

Option Five replaces the '14,200' formula with a formula based on the average ACC throughput (i.e. 6,000 patient episodes per year). The allocation formula is then applied to all patient episodes generated by the APA. This results in a total allocation of around 5,000 licences to providers.

Table 12: Option Five - Allocation based on average ACC throughput and applied to all patient episodes

Key stakeholder groups	Benefits	Costs
Small provider	Increases licence entitlements. Increases the scope for competition and ability to respond to the market.	Increases the cost of serve. Reduces intangible value of assets.
Medium provider	Increases licence entitlements. Increases the scope for competition and ability to respond to the market.	Increases the cost of serve. Reduces intangible value of assets.

[75] KPMG notes that a large number of licences remain unused by the public sector not because there is no demand for them, but because it is argued that current funding arrangements do not provide sufficient revenue to cover the costs of operation (see sections 4.2 and 10.1 for further discussions on this matter).

Key stakeholder groups	Benefits	Costs
Large provider	Increases licence entitlements.	Increases the cost of serve. Partially removes protection of market share. Reduces intangible value of licences.
Government	Potentially increases licence revenue.	May increase pressure on the MOU.
Consumers	Increases access and choice.	

8.5.1 Benefits of Option Five

By reducing the number of patient episodes required for an additional licence entitlement, Option Five will increase the licence entitlement per service provider, thus increasing access to entitlements. At the same time it will facilitate easier access to additional licences as 6,000 patient episodes has been calculated to represent the average throughput of an ACC. This should create a more even playing field between small and large players, and hence a more competitive industry.

As Option Five applies the formula across all patient episodes there are a number of advantages (as compared with Option Four above):

- it treats public and private providers equally; and
- it provides those providers who currently do not use or have a collection centre licence with opportunities for a licence should they need one in the future.

Additional ACCs will increase access and choice for consumers, thus leading to improved health outcomes for the community.

8.5.2 Costs of Option Five

As with Option One there is the potential short run increases in ACC numbers and increase in cost of serve, which may result in increasing cost pressure on the MoU. Again, we consider this to be a temporary and marginal increase in pressure, as the industry adjusts to the new allocations and commercially unsustainable ACCs cease operations.

Given the additional licences created under this allocation method, this option may increase licence revenue for the Government. However as noted in section 7.6, KPMG recommends the current licence tax be abolished and replaced with a fee reflective of the licence scheme administration costs. Therefore to the extent that the licence fee decreases, total Government revenue may also ultimately fall.

8.6 Option Six – Allocation based on average throughput of ACC on recognised regional basis

Option Six replaces the '14,200' formula with a formula based on the average ACC throughput for a designated region. This means APAs may only use the patient episodes generated in a particular region to establish ACCs in that region. Given variations in demographics, Option Six will require different formulae (patient episode benchmarks) depending on the region.

Table 13 illustrates the likely benefits and costs of this option to a range of pathology stakeholders.

Table 13: Option Six – Allocation based on average throughput of ACC on recognised regional basis

Key stakeholder groups	Benefits	Costs
Small provider	Increases ability to compete within an individual region.	Reduces ability to expand across geographic borders. Increases the licence fee because increased government administration.
Medium provider	Increases ability to compete within an individual region.	Reduces ability to expand across geographic borders. Increases the licence fee because increased government administration.
Large provider		Partially removes protection of market share. Reduces ability to expand across geographic borders. Increases the licence fee because increased government administration.
Government		Increases pressure on the MOU because of rising costs. Increases the cost of administration (significantly)
Consumers		Potentially some reduction in access

8.6.1 Benefits of Option Six

A major benefit of Option Six is that it will increase the ability of small and medium providers to compete locally with the larger providers, as the regionally-based allocation mechanism acts as a barrier to the national reallocation of collection centres.

8.6.2 Costs of Option Six

A major concern with this option is that it reduces the ability of providers to expand across geographic borders, and hence respond to market demand. This is because the temporary floor only applies to new entrants.

In addition, given the complexity of the allocation system, this option would be costly to implement and hence result in higher costs to industry in terms of licence fees.

8.7 Summary

A difficulty with NCP reviews such as this is that, in assessing various options, it is necessary to consider a wide range of impacts, many of which are difficult to quantify. In recognising the need to provide a common scale of measurement for all impacts KPMG has chosen to use the 'balanced scorecard' approach. The 'balanced scorecard' approach overcomes the limitations of conventional financial analyses through the following two-step approach.

- Step One involves identifying a range of impacts associated with the various allocation methods considered above.

- Step Two involves allocating a qualitative score for each impact depending on the scale of the identified impact. For example, in conducting this analysis KPMG has assigned a score between +3 (a significant positive effect) and -3 (a significant negative effect) depending on the scale of the impact.

KPMG has identified the following criteria as an appropriate basis for the assessment of each option:

- *Efficiency:* There are three concepts of efficiency, and a truly efficient regulatory regime facilitates each of these outcomes:

  - Productive efficiency requires that the output of the firm be produced at least cost for a given level of quality.

  - Allocative efficiency occurs when scarce resources are allocated to the production of the goods and services most valued by society.

  - Dynamic efficiency requires that efficiency improves over time in response to industry changes and innovation in management.

- *Equity:* The regulatory regime should be equitable for all industry participants, regardless of size, location and ownership structure.

- *Access:* The necessary resources for the provision of quality pathology services are available in the locations required by the community.

- *Cost effectiveness:* To the extent possible, and given the established level of regulation required for the industry, the chosen option should be simple to administer and not costly to implement.

- *Competition:* Again to the extent possible, and given the established level of regulation required for the industry, the chosen option should facilitate competition between industry players regardless of size, location and ownership structure.

To reiterate, the options analysed by KPMG are:

- Option One – no allocation of licences;

- Option Two – current allocation method;

- Option Three – allocation based on growth in all patient episodes;

- Option Four – allocation based on average throughput of ACC applied to ACC patient episodes only;

- Option Five – allocation based on average ACC throughput applied to all patient episodes; and

- Option Six – allocation based on average throughput of ACC on recognised regional basis.

Table 14 provides sets out the expected impacts of the proposed option, assuming that each impact is of equal importance . As shown, Option 1 and Option 3 are clear standouts.

Table 14: Assessment of Reform Options (unweighted)

Impact	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
Efficiency	+2	-2	-3	-3	+1	-2
Equity	+3	-2	-2	-3	+1	-2
Access	+1	0	-1	-1	+1	-1
Cost effectiveness	+1	0	-2	-1	0	-3
Competition	-1	-1	+1	-2	-1	-3
Total score	**+6**	**-5**	**-7**	**-10**	**+2**	**-11**

While Table 14 assumes that each impact is equally as important as the next, in practice however some impacts are relatively more important than others. As shown in Table 15 KPMG has assigned weightings to each impact. These weightings have essentially been developed from objectives outlined in section 5.2 and discussions with stakeholders.

Table 15: Assessment of Reform Options (weighted)

Impact	Weighting	Option 1	Option 2	Option 3	Option 4	Option 5	Option 6
Efficiency	15%	0.3	-0.3	-0.45	-0.45	0.15	-0.3
Equity	25%	0.75	-0.5	-0.5	-0.75	0.25	-0.3
Access	25%	0.25	0	-0.25	-0.25	0.25	-0.15
Cost effectiveness	10%	0.1	0	-0.2	-0.1	0	-0.45
Competition	25%	-0.25	-0.25	0.25	-0.5	-0.25	-0.45
Total score	**100%**	**1.15**	**-1.05**	**-1.15**	**-2.05**	**0.4**	**-1.65**

Given the above weightings the preferred option for reform is Option One – No allocation method. This option clearly comes out ahead of the other options, with the second best option being Option Five – Allocation based on average ACC throughput and applied to all patient episodes. This is not a surprising result given that the revised allocation under Option Five results in approximately 5,000 licences available to providers, with such a large pool of entitlements having basically the same effect as unrestricted licence numbers.

Given Option One emerges with the highest total and is aligned with the principle of "minimum efficient regulation", KPMG considers that the objectives of collection centre regulation are best met by removing the licence restrictions.

Recommendation Seven – There should be no allocation method for licences.

9 Conclusions

This chapter summaries the key findings and the recommended option for future regulation of collection centres. It also provides details on a process for implementing any future changes to the regulatory framework.

9.1 Key recommendations

The key recommendations stemming from the review are as follows.

Recommendation One - KPMG recommends that all types of laboratories be eligible for collection centres, subject to being owned by an APA.

Recommendation Two - KPMG recommends that clause 4 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* be amended to specify that appropriate quality standards must be met.

Recommendation Three - KPMG recommends that all collection centres be subject to more uniform and greater quality control mechanisms.

Recommendation Four - KPMG recommends that, should licences continue to be restricted, a temporary floor of seven be introduced. The licence floor should remain in place for five years.

Recommendation Five - The method of providing access to pathology collection centres in rural and remote areas should be reviewed in light of the outcomes of the RRMA review. Should restrictions on licences be removed, consideration could be given to introducing other policy mechanisms aimed at ensuring access to pathology collection centres in rural and regional areas.

Recommendation Six - Fees for licences should be reviewed so that, in addition to being based on cost recovery principles, they do not unnecessarily create barriers to entry for small firms or individuals.

Recommendation Seven – Based on National Competition Policy principles, there should be no allocation method for licences. Hence, there will be no requirement for a licence floor.

Hence, the future regulatory arrangements for ACCs should include the following:

- a licensing regime with eligibility based on:
  - status as an APA; and

- meeting appropriate quality standards;

- specific targeted and transparent provisions to facilitate regional and rural access; and

- licence fees (not taxes) set on a cost-reflective basis.

9.2 Monitoring future impacts

As outlined in Chapter 4 the regulatory arrangements governing pathology testing are interrelated and to some extent duplicative. As such, one of the challenges of the review has been to assess the regulatory arrangements for ACCs in isolation, that is, without consideration of the existing regulatory arrangements for APAs, APPs and APLs. While KPMG has assessed the restrictions against the principles laid down in clause 5(1) of the *CPA*, there is a risk that the current regulatory arrangements for APAs, APPs and APLs may adversely impact on the ACC reforms, because ACCs are only one component of the service continuum.

Although KPMG has identified that the level of market concentration for collection centres currently exceeds the ACC thresholds, no similar analysis has been undertaken for APLs, although the results are likely to be similar. In saying this there is a risk that the reform proposed to increase competition will also increase market concentration. Careful monitoring of industry concentration levels of ACCs and APLs is therefore essential.

Given the issues raised in the report (both by KPMG and stakeholders) and the comments above, KPMG considers that in future, the regulatory arrangements governing the pathology testing process should be done in its entirety. That is, it should review all the regulatory arrangements for APAs, APPs, APLs and ACCs to ensure the arrangements meet the principle of 'minimum efficient regulation'.

10 Matters beyond the scope of the review

As outlined in this report (and emphasised in Appendix A) KPMG was engaged to undertake an NCP review of the ACC arrangements. During the course of the review process KPMG came across a range of issues which are related to the review, but upon consultation with the Department were determined not to be strictly within the Terms of Reference. These are outlined in the following sections.

10.1 PEI

One form of fee provided for in the PST is a patient episode initiation (PEI) fee.[76] The PEI was introduced in 1992 as part of the LCC Scheme to compensate an approved collection body (i.e. a LCC or a treating practitioner) for the costs incurred in specimen collection.

Under the current arrangements a private pathology organisation (PPO) is eligible to receive the PEI (the current PEI fee for specimens collected in approved collection centres is $17.40, of which community collection centres receive 85 per cent, amounting to $14.80[77]). However under sections 14(2)(c) and 14(2)(d) of the *Health Insurance (Pathology Service Table) Regulations 2005*, a pathologist employed by a Public Health Organisation (PHO) is not eligible for the PEI.

It is claimed that the rationale for distinguishing between the two classes of eligibility was that a pathologist employed by a PHO was provided with certain infrastructure (such as collection centres, couriers, etc) at no cost to themselves, while a pathologist employed by a PPO was required to meet all these non-testing costs.

Despite this claim, there remains some debate over the costs that the PEI was intended to cover. For example, it has been reported that the components of costs included in the PEI fees:

> "…represent costs other than those directly involved in the test procedure and include the costs associated with transporting specimens to the laboratory and collecting samples"[78]

However an internal Departmental report dated 1997-98 provided more clarity by stating that the PEI was to cover:[79]

- the overhead costs of the collecting centre;
- staff and equipment;
- transport costs between the patient, collection centre and laboratory;
- storage facilities; and

[76] Category 6, Group 10 of Medicare Benefits Schedule.
[77] Category 6, Group 10 of Medicare Benefits Schedule
[78] Supplement to Medicare Benefits Schedule Book of 1st December 1991, effective 1st February 1992, ;page 3, under PE. SCHEDULE FEES as reported by NCOPP in its submission to the review.
[79] Directions for Pathology, 1997-98, Internal Department of Health report.

- quality control, LCC inspection and licensing.

While the distinction between the two classes of pathologists remain clear, the lines begin to blur when pathologists employed by a PHO choose to exercise their rights of private practice (ROPP). Using the example of NSW, NCOPP emphasised that individual pathologists employed by a PHO exercising their ROPP:

- are required to be registered to pay GST, and to have an ABN;
- generate revenue that is taxable in the hand of the individual pathologist. The PHO is not a recipient of this money; and
- are required to pay a Management Fee ("Infrastructure Fee") to the PHO to cover rent use of equipment, staff, marketing, education, collection, rent for collection centres, transport, report delivery, invoicing, receipting, etc.

NCOPP also emphasises that these arrangements apply regardless of whether the individual pathologist operates in solo practice, or practising as part of a partnership or other group.

Furthermore, given that the ACC arrangements apply to both private and public pathology providers, NCOPP notes that public pathology laboratories are now permitted to enter the community marketplace. In doing so, they engage in marketing, education, collection. transport, report delivery, invoicing, receipting, etc – activities it is claimed, that the PEI was intended to cover.

Based on these arguments NCOPP claims that:[80]

> "It effectively prevents Pathologists employed by public pathology organisations, but exercising their Rights of Private Practice, from entry into the community marketplace due to their receiving 25% lower fees than their counterparts employed by private pathology organisations conducting identical business and providing identical services. It also ensures there is a high barrier to entry to the community marketplace, thus dividing the market into two segments, and denying access of Pathologists employed by public pathology organisations to the major segment of this market."

KPMG notes that the current MOU provides for the phased introduction of PEI fees for public sector accredited pathology laboratories, which will be introduced on 1 May 2007 at $2.40 per item (subject to the appropriate Parliamentary processes).[81] Section 8 of the 2004-09 MoU proposes the phased introduction of the PEI so that public pathology will become eligible for PEI fee reimbursement, identical to that existing for private pathology homologues.

Consultation has revealed that private providers are not opposed to public sector accredited laboratories being eligible for the PEI, so long as their eligibility does not affect the current PEI payments.

[80] NCOPP submission to the NCP Review of the Current Arrangements for Approved (Pathology) Collection Centres, 16 June 2006
[81] Pathology Quality and Outlays Memorandum of Understanding, 2004

Despite the PEI being deemed outside the scope of this review KPMG notes that there are some issues in this area.

The Australian Government is aware that the public sector, by virtue of its government ownership, may experience a range of advantages over its private sector counterparts. As a way of offsetting these competitive advantages the Australian Government expressed a commitment to the implementation of competitive neutrality principles in the *CPA*. It explicitly states that:[82]

> Government businesses should not enjoy any net competitive advantage simply as a result of their public sector ownership.
>
> The objective of competitive neutrality policy is the elimination of resource allocation distortions arising out of the public ownership of entities engaged in significant business activities.

While the aim of competitive neutrality is to even the playing field between private and public sector competitors by eliminating the advantages of public sector ownership, NCP is broader focussed on increasing competition. This implies that no sector, whether public or private should be placed at a competitive disadvantage simply based on its ownership status.

It is for this reason that KPMG believes the issue of the PEI should be revisited. Two steps need to be taken: firstly determine exactly what the PEI is to cover; and then set it to recover an efficient level of those costs.

10.2 Payment of non-commercial rents

Some industry stakeholders indicated that non-commercial rents were being paid to secure prime collection centre locations (i.e. within or adjacent to GP practices) and thus secure these referral streams.

With limits on the maximum number of ACC licences an APA can operate, each pathology provider seeks to maximise their returns by placing collection centre in locations that will secure the maximum number of referrals. As such, there is a high level of competition for these sites. Hence limits on licences can create incentives for providers to compete in other areas (such as payments of above market rates) with a view to securing valuable referral streams.

These allegations are not new, with the submissions to Phillips Fox alleging similar behaviour. As a result it was recommended that:[83]

> The HIA include an express statement to the effect that one of its objectives is to ensure that any purported gift, fee or other consideration in any transaction in which an APA/APP (or parties with relevant connection to them) is on one side of the transaction and a practitioner/medical entrepreneur (or parties with a relevant connection between them) is on another side of the transaction meets a 'normal commercial rates' test (Recommendation 13.1).

[82] Clause 3, Competition Policy Agreement
[83] Phillips Fox, 2005, *Review of Enforcement and Offence Provisions of the Health Insurance Act 1973 as they Relate to the Provision of Pathology Services Under Medicare: Final Report to the Department of Health and Ageing,* p.61.

The HIA include a test for 'normal commercial rates', modelled on the existing test for normal commercial rates in relation to leasing floor space, to be applied to all transactions between, on the one hand, APA/APPs (or parties with a relevant connection with them) and on the other hand a practitioner/medical entrepreneur (or parties with a relevant connection with them) (Recommendation 13.2).

Before an APA/APP (or parties with a relevant connection with them) on one side of the transaction and a practitioner/medical entrepreneur (or parties with a relevant connection to them) on another side of the transaction enter into or vary a transaction, the APA/APP obtain and provide to the Minister a sworn valuation from a relevantly qualified valuer confirming that the rate under the arrangement or under the variation as the case may be is in accordance with the normal commercial rate (Recommendation 13.3).

The Australian Government, in its response to the Recommendations of the Phillips Fox Review, has given support to these recommendations for a limited range of transactions and stated it "will give specific attention to the issue of existing rental agreements and how such agreements should be treated during the phase in period."[84]

10.3 Co-location of ACCs in GP practices

During our consultation phase, many stakeholders raised the co-location of GP practices and ACCs as an issue of concern. Following Government initiatives to encourage the amalgamation of GP practices, it has become increasingly common for ACCs to be co-located with these large practices, as they generate a referral stream sufficient to warrant an on-site pathology collection centre. Furthermore, vertical integration of pathology providers and GP practices has also led to business decisions to collocate GP practices and ACCs owned by the same corporation.

This has raised several areas of concern for some stakeholders as follows:

- to secure prime locations, some pathology service providers will provide inducements for GPs, such as excessive rent, IT support or marketing services;
- pathology service providers that are part of large corporations may legally provide a nurse to a GP practice owned by the same corporation, whereas this would be considered an inducement if provided by an independent pathology provider;
- the legislation should be changed to prevent collection centres within GP practices because the GPs have a conflict of interest; and
- Collocation with GP clinics will actually increase the use of pathology services because they are more accessible.

The first issue of GP referral inducement is addressed in section 10.2. The second and third issues have been covered in the Phillips Fox review, and a brief summary of the relevant conclusions is provided in this section. Regarding the last concern, the 'Drivers of Growth'

[84] Minister for Health and Ageing, 2006, *Australian Government Response to the 2004 Review of Enforcement & Offence provisions of the Health Insurance Act 1973 (HIA) as they relate to the Provision of Pathology Services Under Medicare*, AGPS, Canberra, p.12.

study which has recently been commissioned by the Department should provide more insight into the outcomes of the collocation of GP clinics and ACCs.

10.3.1 Corporatised GP clinics and pathology providers

Regarding the second concern, stakeholder submissions to the Phillips Fox review alleged that there were cases where by pathology providers were supplying:

> (T)he services of nursing or administrative staff to assist requesting practitioners with the collection (and / or administrative management of the collection) of pathology samples.[85]

The Phillips Fox review investigated provisions in *HIA* designed to prevent over-servicing, bribery and prohibited practices provisions. However, the Review Team concluded that the wording of these provisions could probably not be relied upon to lift the corporate veil. Accordingly, the Review Team recommended the provisions be extended to situations where: [86]

> An APA or an APP has an interest in a company or trust and the medical practitioner and / or medical entrepreneur has an interest in the same company or trust, and the company provides some service or facility to any one or more of the APA, the APP, the medical practitioner, the medical entrepreneur or any company or trust in which any one of them has an interest (recommendation 24).

In its response to the Phillips Fox Review, the Australian Government agreed with the intent of this recommendation and the drafting of the revised legislation will include (among others) this point.[87]

10.3.2 Conflicts of interest

Submissions to the Phillips Fox review outlined concerns that:

> (I)t is unprofessional and / or unethical for a requesting practitioner to be a situation in which they may have interests in both the patient's welfare and the extent to which they personally are, or will be, provided with financial or in-kind support by a pathology provider. [88]

However as part of the review it was stated that: [89]

> The Review Team considers that the professional and ethical conduct of medical practitioners is regulated most appropriately through the existing arrangements at a State and Territory level, rather than through Commonwealth legislation that is designed to facilitate the efficient administration of the Medicare system, and that the HIA should not be used to advance an

[85] Phillips Fox, 2005, *Review of Enforcement and Offence Provisions of the Health Insurance Act 1973 as they Relate to the Provision of Pathology Services Under Medicare: Final Report to the Department of Health and Ageing,*
[86] ibid,, p.69.
[87] *Australian Government Response to the 2004 Review of Enforcement and Offence Provisions of the Health Insurance Act 1973 as they Relate to the Provision of Pathology Services Under Medicare,* 2006, p.15.
[88] Phillips Fox, 2005, *Review of Enforcement and Offence Provisions of the Health Insurance Act 1973 as they Relate to the Provision of Pathology Services Under Medicare: Final Report to the Department of Health and Ageing,* p.51.
[89] Phillips Fox, 2005, *Review of Enforcement and Offence Provisions of the Health Insurance Act 1973 as they Relate to the Provision of Pathology Services Under Medicare: Final Report to the Department of Health and Ageing,* p.51.

objective of preventing requesting practitioners from being in conflict of interest situations when requesting pathology services.

A Terms of reference

1. Examine the regulatory framework of the approved pathology collection centre (ACC) arrangements to determine whether it is consistent with the objectives of the National Competition Policy, with particular attention to:

   - The objectives expressed at the time of introduction of revised arrangements in 2001;
   - Stakeholder views on the current arrangements in achieving the stated objectives
   - The success or otherwise of the current arrangements in achieving the stated objectives
   - Any unintended consequences of the current arrangements; and
   - Any differential effects of the current arrangements on particular classes of providers of pathology services (eg private sector, public sector, corporate providers, not-for-profit providers, "niche" providers).

2. Assess the costs and benefits of the current arrangements – and in particular provide an assessment of whether restrictions on competition are warranted in terms of any public benefits that they might produce.

3. To the extent that there are continuing public benefits from restrictions on competition, consider the case for achieving these benefits through alternative means including:

   - Non-legislative approaches
   - More pro-competitive approaches
   - Approaches involving a lesser degree of regulation

4. If it is determined that a regulatory framework is required for the ACC arrangements, identify the objectives of an optimal regulatory framework.

5. A range of options that address any competition issues and problems raised by stakeholders during the review are to be developed for consideration

6. The costs and benefits of each of the options including the maintenance of the current arrangements are to be analysed

7. The effect on stakeholders of any proposed changes in the regulatory framework is to be identified

8. A detailed conclusion of the review including a recommended option is to be provided in the final report

9. A process for implementing any changes to the regulatory framework and an outline of mechanisms or measure for assessing the ACC arrangements in the future is to be developed.

B Stakeholders consulted

In addition to the Department of Health and Ageing, KPMG consulted with the following stakeholders.

Pathology Consultative Committee

David Kindon	AAPP
Michael Harrison	AAPP
Michael Guerin	AAPP
Debra Graves	RCPA
Bev Rowbotham	RCPA
Tamsin Waterhouse	RCPA
Scott Jansson	NCOPP
Doug Marshall	Medicare Australia

Industry stakeholders

Ed Wilson	AAPP
John O'Dea	AMA
Tim Blanche	ARL Pathology
Paul Santoro	ARL Pathology
John Callahan	Bayside Pathology
Jonathan Cohen	Caulfield Family Medical Practice
Mark Cawthorne	IMVS
Tony Solace	Independent Diagnostic Services
Colin Ades	IQ Pathology
Julie Hudson	Mater Misericordiae Health
John O'Donnell	Mater Misericordiae Health

Dr John Hinds	Mater Pathology
Dr Peter Charlton	Medicare Australia
Ms Elizabeth Low	Medicare Australia
Lez Moaven	Moaven and Partners
Professor Leslie Burnett	NCOPP
Peter Flett	Pathwest
Stewart Bryant	RCPA
Gary Lum	Royal Darwin Hospital
Kevin Taylor	St John of God (Pathology)
Fred Humphreys	St Vincent's Pathology, Melbourne
Jeff Searl	St Vincent's Pathology Melbourne
Kerry Stubbs	St Vincent's Hospital, Sydney
Michael Harrison	Sonic Health Ltd
Nikki Thrift	South Coast Independent Pathology
Serge Peric	South Coast Independent Pathology
David Hodgson	SydPath
Robert Cooke	Symbion Health
Anoop Singh	Symbion Pathology
Ann Taylor	Symbion Pathology

C Submissions received

Official written submissions were received from the AAPP and NCOPP.

D Competitive restrictions

D.1 Restrictions on eligibility

Clause 5 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* states that:

(1) An application for approval of an eligible collection centre must not be considered by the Minister unless it is made:

(a) by an APA who is an eligible applicant; and

(b) in writing and in the prescribed form.

(2) For subsection (1), an APA is an eligible applicant if the APA:

(a) operates, and is the sole owner of, an accredited pathology laboratory that is a category G pathology laboratory; or

(b) has entered into an arrangement with another APA for the use of an accredited pathology laboratory that is a category G pathology laboratory and, immediately before the commencement of item 31 of Schedule 1 to the Amendment Act, operated a collection centre that:

(i) was not located on the hospital premises of a recognized hospital; and

(ii) was in an area that, in the Rural/Remote Areas Classification, is:

(A) a Rural Major statistical local area; or

(B) a Rural Other statistical local area; or

(C) a Remote Major statistical local area; or

(D) a Remote Other statistical local area; or

(c) is an APA who

(i) operates, and is the sole owner of, an accredited pathology laboratory that is a category S pathology laboratory that is proposing to collect solely specimens within its specialty; and

(ii) immediately before the commencement of item 31 of Schedule 1 to the Amendment Act, was the holder of a unit of entitlement to operate a licensed collection centre; or

(d) operates, and is the sole owner of, an accredited pathology laboratory that is category S pathology laboratory

(i) is proposing to collect solely specimens within its speciality; and

(ii) will be located on same premises as the collection centre that is the subject of the application; and

(iii) received accreditation as a category S laboratory after the commencement of item 31 of Schedule 1 to the Amendment Act.

(3) An application must be supported by:

(a) all information reasonably required by the Minister to enable the application to be decided; and

(b) a written undertaking that the applicant will comply with the Collection Centre Guidelines in operating a collection centre for which an approval is in force, except to the extent that, in a particular circumstance, the Minister accepts that compliance with some, or all, provisions of the Guidelines is not reasonably practicable.

D.2 Restrictions on standards of operation

Clause 4 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* states that:

An application for approval of an eligible collection centre must not be considered by the Minister unless the premises to be occupied by the specimen collection centre meet the following criteria"

(a) there is on premises the necessary equipment for the collection and preparation of specimens for pathology procedures; and

(b) The staff at the premises;

(i) are persons employed by the APA; and

(ii) include persons properly trained in procedures for the collection and preparation of pathology specimens.

D.3 Restrictions on the number permitted to be operated

D.3.1 Generic restrictions

Clause 11 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* states that:

(1) An APA may be granted the maximum number of approvals determined under this section if:

(a) it is an APA to which paragraph 5(2) (a) applies; and

(b) for the 2 full consecutive calendar years immediately preceding the calendar year in which the application for approval is made, it has:.

(i) operated an accredited pathology laboratory that is a category G pathology laboratory; and

(ii) been the sole owner of the laboratory.

(2) Subject to subsection (3), the maximum number of approvals that the APA may be granted under this section is determined:

(a) by dividing, by 14200, the number of patient episodes for which the APA provided a pathology service, or services, during the calendar year immediately preceding the calendar year in which the relevant financial year commences; and

(b) if the result includes a faction, by rounding it to the nearest whole number and, in the event of the fraction being 0.5, by rounding up.

(3) For an APA that proposes to operate an eligible collection centre in the same premises as it operates a category G pathology laboratory in the relevant financial year, the maximum number of approvals is increased by one for each eligible collection centre that it proposes to operate in the same premises as it operates a category G pathology laboratory.

Clause 12 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* states that:

(1) An APA may be granted the maximum number of approvals determined under this section if:

(a) it is an APA to which paragraph 5(2) applies; and

(b) it is not an APA to which section 11 applies.

(2) Subject to subsection (4), the maximum number of approvals that the APA may be granted under this section is:

(a) if the APA has operated, and been the sole owner of, an accredited pathology laboratory that is a category G pathology laboratory for less than the full calendar year immediately preceding the calendar year in which the application for approval is made - 2; and

(b) if the APA has operated, and been the sole owner of, an accredited pathology laboratory that is a category G pathology laboratory for the full calendar year in which the application for approval is made, but less than the period mentioned in paragraph 11(1)(b) – the higher of the following

(i) the number worked out under subsection (3);

(ii) 2.

(3) For subparagraph (2)(b)(i), the number is determined:

(a) by dividing, by 14200, the number of patient episodes for which the APA provided a pathology service, or services, during the calendar year immediately preceding the calendar year in which the relevant financial year commences; and

(b) if the result includes a faction, by rounding it to the nearest whole number and, in the event of the fraction being 0.5, by rounding up.

(4) For an APA that proposes to operate an eligible collection centre in the same premises as it operates a category G pathology laboratory in the relevant financial year, the maximum number of approvals is increased by one for each eligible collection centre that it proposes to operate in the same premises as it operates a category G pathology laboratory.

Clause 13 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* states that:

The maximum number of approvals that may be granted to an APA to which paragraph 5(2)(b) applies is the number that is equal to the number of specimen collection centres that:

(a) the APA was operating immediately before the commencement of item 31 of Schedule 1 to the Amendment Act; and

(b) were not located on the hospital premises of a recognized hospital.

Clause 14 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* states that:

The maximum number of approvals that may be granted to an APA to which paragraph 5(2)(c) applies is the number that is equal to the number of licensed collection centres that the APA was operating immediately before the commencement of item 31 of Schedule 1 to the Amendment Act.

Clause 15 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* states that:

The maximum number of approvals that may be granted to an APA to which paragraph 5(2)(d) is one for each of the premises on which the APA operates a category S pathology laboratory of the kind described in paragraph 5(2)(d)

D.3.2 Exceptions

Clause 10 of the *Health Insurance (Eligible Collection Centres) Approval Principles 2005* states that:

(1) In this Part, a reference to an approval is taken, at the election of the holder, to be a reference to 2 or 3 approvals if those approvals are applied by the holder of the operation of eligible collection centres in locations that, in the Rural/Remote Areas Classification, are

(a) Rural Other statistical local areas; or

(b) Remote Other statistical local areas.

(2) Subsection (1) does not apply to an approval the grant of which is allowed by operation of subsection 11(3) or 12(4)

(3) Subsection (1) ceases to have effect if an approval applying to an eligible collection centre mentioned in that subsection is applied, by transfer or by any other circumstance, to a collection centre that is not a collection centre mentioned in that subsection.

D.4 Restrictions on price

D.4.1 Price levels

Section 4A of the *Health Insurance Act 1973* states:

(1) The regulations may prescribe a table of pathology services table that sets out the following:

(a) items of pathology services;

(b) the amount of fees applicable in respect of each item;

(c) rules for interpretation of the table.

The table, including lists of the items of pathology services and the amount of fees applicable for each item is set out in the *Health Insurance (Pathology Services Table) Regulations 2005.*

D.4.2 Payment of Medicare benefits

Under section 16A(5AA)(d)(i) of the *Health Insurance Act 1973* the payment of Medicare benefits in relation to a pathology service is not payable unless the pathology specimen required for the rendering of the service was collected from the person by a person at an approved collection centre