



**Australian Government**  
**Department of Health and Ageing**

**REVIEW OF THE FUNDING ARRANGEMENTS FOR  
PATHOLOGY SERVICES**

**FINAL DISCUSSION PAPER**

This Discussion Paper has been prepared by the Department of Health and Ageing as a basis for consultation with pathology stakeholders. These consultations will inform the development of advice to the Minister for Health and Ageing, the Hon Nicola Roxon MP, regarding options for future funding of pathology services.

This Paper has been developed to guide consultation and discussion by providing an overview of some of the issues identified in respect of the current funding arrangements and to help identify possible alternative options for consideration. These options have not been endorsed by the Department of Health and Ageing, the Minister or the Australian Government.

Any queries in relation to the contents of this Discussion Paper can be directed to the Medical Benefits Reviews Task Group at [mbrtg@health.gov.au](mailto:mbrtg@health.gov.au).

**Medical Benefits Reviews Task Group**  
**Department of Health and Ageing**  
**March 2011**

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# 1 Review of the Funding Arrangements for Pathology Services

## Introduction

The government has requested a detailed Review of Pathology Funding Arrangements to ensure that the government is paying the right amount to support access for patients to quality pathology services.

The detailed Review of Funding for Pathology Services will focus on pathology services currently funded through the Medicare Benefits Schedule.

## Terms of Reference

The Review of pathology has three key tasks:

- To establish appropriate fee relativities for Medicare Benefits Schedule (MBS) items for different disciplines;
- To identify groups of pathology tests that might be appropriate for different funding arrangements; and
- To provide detailed options for implementing tendering for selected pathology services.

The Review will not focus on issues around the requesting of and demand for services, except where this is relevant to considering how services are funded.

The Review will consider some specific issues regarding rural and remote service provision, including whether current arrangements support long-term viability of pathology services, and consideration of options for addressing any identified issues.

The Review involves extensive consultation with a wide range of stakeholders, through formal committees, and submissions, forums and bilateral meetings.

The full Terms of Reference for the Review are available at the department's website <http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Pathology>.

## Formal Consultation

The Pathology Review Consultation Committee (PRCC) was established in December 2009 to enable pathology stakeholders to contribute effectively to the review process. Input from pathology stakeholders is vital to ensure that the review process is fully informed of relevant issues by providers, requesters and consumers of pathology.

The role of this Committee is to:

- Promote awareness of the Review throughout the pathology industry and profession;
- Canvass views of their organisations to ensure the department with fully informed of issues relevant to their organisation;
- Assist, where possible to help the department to compile evidence to support, or not support, a series of options on the future funding of pathology, in line with the Terms of Reference of the Review;
- Assist, where possible, in data collection to provide appropriate costing for options that are

developed; and

- Work with the department to achieve the objectives of the Review in the timelines provided.

The Committee's Terms of Reference, as well as a list of the stakeholder groups who are represented on the Committee is provided on the department's website:

[http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Pathology\\_PRCC](http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Pathology_PRCC).

Committee meetings have taken place on 31 March, 16 June and 9 November 2010. The minutes from these meetings can be found at:

[http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Pathology\\_PRCC](http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Pathology_PRCC).

The MBRTG has also met with stakeholders at bilateral meetings, to more fully understand the specific opinions of the sector. Summaries of these meeting can be found at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRTG+-+Pathology+-+Stakeholder+Engagement>.

### **First Pathology Discussion Paper**

A preliminary Discussion Paper was developed and distributed in January 2010 to provide an overview of some of the existing funding arrangements and to encourage stakeholders to provide innovative input and help to identify possible alternative options for consideration. A copy of that Discussion Paper can be found at:

[http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Pathology\\_Discussion1](http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Pathology_Discussion1).

### **Final Pathology Discussion Paper**

This is the final Discussion Paper of the Pathology Review. It has been prepared by taking into account stakeholders' views on the proposals raised in the first Discussion Paper as well as other proposals identified, and attempts to refine these options and provide a more focused vision for the way forward. This Discussion Paper is seeking comment from all interested stakeholders on these proposals.

### **Submissions**

Stakeholders are invited to provide written submissions addressing all, or selected, issues raised in this Discussion Paper, by **25 March 2011**. Consistent with the first Discussion Paper, submissions received will be made publicly available unless confidentiality is specifically requested and justified. Written submissions should be sent to the following address:

Pathology Review  
Medical Benefits Reviews Task Group  
Department of Health and Ageing  
MDP 950  
GPO Box 9848  
CANBERRA ACT 2601

Alternatively, stakeholders may choose to provide their submission through e-mail to the Medical Benefits Reviews Task Group at: [mbrtg@health.gov.au](mailto:mbrtg@health.gov.au).

For further information regarding this Discussion Paper or to arrange a bilateral meeting to discuss any aspect of the Review please contact the Medical Benefits Reviews Task Group through the e-mail address above.

## **Further Consultations**

The MBRTG will continue consulting with the PRCC and will be undertaking further bilateral meetings.

## **Next Steps**

Following analysis of responses to this Discussion Paper and the next round of stakeholder consultations, the department will provide the Minister for Health and Ageing with options for consideration by government. It is expected that the government's decision in response to the Review will be reflected in the 2011-12 Budget.

## 2 Summary of Submissions to the First Discussion Paper

### Overview

The department was pleased with the number of responses that it received in response to the first Discussion Paper, demonstrating the willingness of the sector to contribute to the changing health environment.

Twenty nine submissions were received, including: eleven responses from professional associations; three responses from groups of medical specialists; and four state government responses.

Based on the number of respondents that made comment, the key themes of the submissions were: tendering (72.4%); the episode cone (58.6%); the common core requirements to maintain high quality pathology services (55.2%); whether current MBS fees adequately reflect costs (51.7%); performance-based payments (51.7%); and point of care testing (51.7%).

Access to the full range of individual submissions is available on the department's website, along with a summary of the submissions, at: <http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Pathology-submissions>.

### Executive Summary

There were many differing and contradicting views about fee relativities for specific pathology disciplines, noting that some individual items may be over or under-remunerated. The existing MBS fee-for-service model was generally supported but additional models of payment in addition to fee-for-service were not entirely discounted.

The issue of tendering was the most controversial. Most respondents were strongly against monopoly tendering specifically, and there was also significant input explaining that the complexities of pathology means development of adequate tender specifications would be difficult. On the other hand, there were some responses that stated tendering for specialised fields of pathology, such as genetics, would be feasible, with block funding rather than a fee-for-service funding model.

The majority of submissions were in favour of removing the episode cone. There were suggestions that increased expenditure could possibly be recouped through other methods.

Most of those that provided comments on episodic panels were supportive. The concept of performance-based payment was also supported. Neither concepts of component payment nor splitting payment based on professional input were strongly supported by stakeholders. Similarly, the Patient Episode Initiation (PEI) did not generate strong views from stakeholders. Many submissions were supportive of the existing fee-for-service pathology model, which has provided a relatively stable environment and provides access for the majority.

Mixed views were provided on the potential impact of the removal of restrictions on Approved Collection Centres (ACCs) and it was acknowledged that it is difficult to predict as these restrictions had not been lifted at that time.

The topic of point of care testing created mixed responses from stakeholders. Many considered that this model would be appropriate in rural and remote areas.

There were no strong views about providing rewards for innovation.

### 3 Analysis of Pathology in Australia

The government has made it clear that it wants to ensure that patients have continued access to quality, affordable pathology services. The government is also keen to ensure that it is paying the right amount in the right way to support this objective. This is consistent with the government's broader commitment to responsible financial management.

There is a distinction between pathologists, as the medical specialists responsible for quality provision of pathology services that underpin patient diagnosis and management, and the corporate, non-corporate and public providers who employ pathologists.

The Pathology Review has undertaken an analysis of the current state of pathology in Australia, its strengths and weaknesses, and opportunities to ensure sustainability of the sector into the future. This will provide context around the proposals chosen for going forward.

#### 3.1 Existing Pathology Environment

The Royal College of Pathologists of Australasia (RCPA) defines pathology as the medical specialty concerned with the study of the nature and causes of diseases<sup>1</sup>. It underpins every aspect of medicine, from diagnostic testing and monitoring of chronic diseases to cutting-edge genetic research and blood transfusion technologies. Pathologists diagnose every detected cancer in the world.

Pathology is described as the scientific basis of medicine. It began with the study of anatomy, but modern pathology began with the invention of the microscope leading to greater understanding about tissues, blood and other bodily fluids.

Pathology is used to make a diagnosis e.g. anaemia, diabetes, swine flu, meningococcal disease, cancer and genetic abnormality. It plays a critical role in more than 70% of clinical diagnoses and in many of the decisions made about the optimal treatment for patients. The original test, or further testing, may well indicate the disease prognosis or dictate disease management pathways. Patients under care may well need follow-up testing to confirm or alter medical management or pharmaceutical dosage.

As new disciplines arose around the study of blood (haematology), with the technology of organic chemistry (chemical pathology) and the discovery and study of micro-organisms (microbiology), pathology separated into separate discipline areas as reflected in the Pathology Services Table (PST). These discipline areas still exist in some laboratories, but with increasing technology that crosses discipline boundaries most laboratories are comprehensive in the range of services they offer and the classical discipline boundaries are smudged by work-flow, common technology and processes. However, specialist pathologists and scientists are situated in areas of their special focus, testing and technology.

#### Disciplines of Pathology

There are a number of different disciplines of pathology:

- **Anatomical Pathology**, which deals with the tissue diagnosis of disease (Histopathology) and the microscopy of cellular samples (cytopathology). For this, anatomical pathologists need a broad-based knowledge and understanding of the pathological and clinical aspects of many

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<sup>1</sup> The Royal College of Pathologists of Australasia: <http://www.rcpa.edu.au/Home.htm> accessed 28 September 2010



diseases. This is the least automated area of the laboratory and has the highest professional component. It is reliant on the skills of the support staff to present tissue to the anatomical pathologist for detailed examination which will lead to diagnosis or determine subsequent management even acute management in a surgical environment.

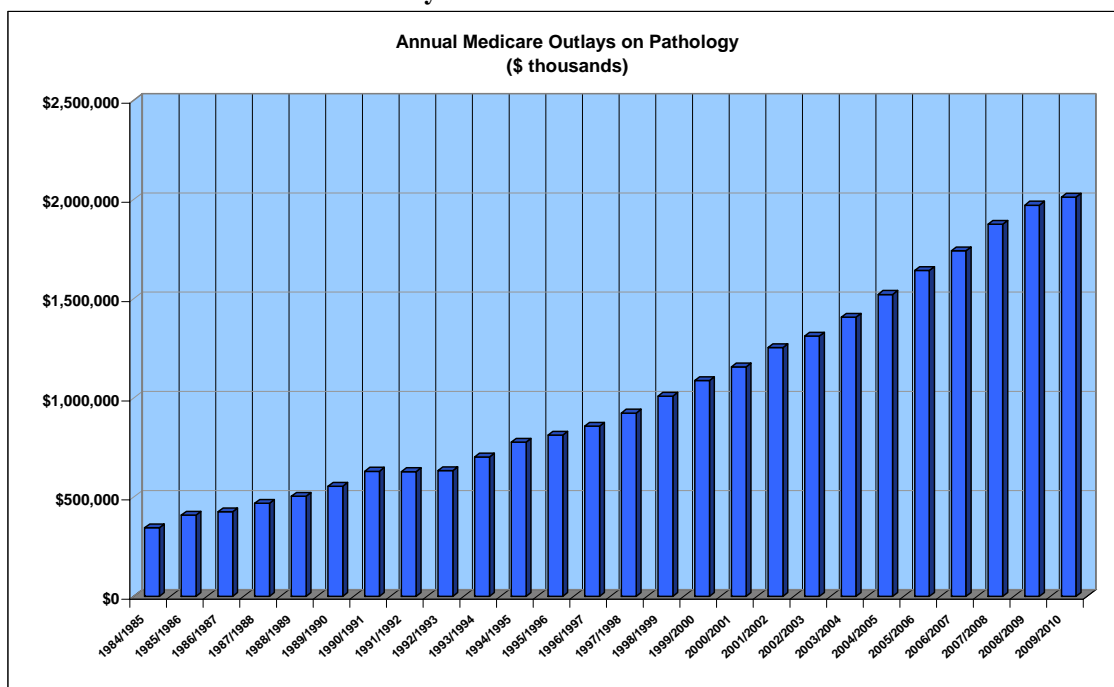
- **Chemical Pathology**, which deals with the entire range of disease. It encompasses detecting changes in a wide range of substances in blood and body fluids (electrolytes, enzymes, proteins, vitamins and hormones) in association with many diseases. In addition, it involves detecting and measuring tumour (cancer) markers, hormones, poisons and both therapeutic and illicit drugs. For example chemical pathologists are involved in assessing levels of iron in the blood, measuring the levels of enzymes that are released into the blood after a heart attack to help in the diagnosis, and in the measurement of certain proteins produced by cancers to monitor the response to their treatment. Whilst any of these tests can be performed individually in support of an acute medical circumstance, the vast majority of these tests are highly automated.
- **Haematology**, which deals with many aspects of those diseases which affect the blood such as anaemia, leukaemia, lymphoma, and clotting or bleeding disorders and is highly automated.
- **Microbiology**, which deals with diseases caused by infectious agents such as bacteria, viruses, fungi and parasites. While advances in technology and molecular medicine (automation, polymerase chain reaction) have added greatly to the microbiologist's diagnostic suite of tools and resources, microbiology remains very much a 'hands-on' discipline. The non-bacteriological and mycology areas of a microbiology lab are able to be highly automated. The areas using culture and microscopy are currently not, but progress is being made on alternate technologies.
- **Immunopathology**, which often involves both laboratory medicine (the testing of specimens collected from patients) and clinical practice (interviewing, examining and advising patients about clinical problems). Most tests on the immunology section of the PST are able to be highly automated, and the volume of work is the major determinant.
- **Genetic Pathology** which is an expertise in interpreting the results of laboratory genetic tests. Genetics is the most recent discipline to emerge in pathology. The revolution in genetics, and current knowledge of genetic disorders, has been precipitated by the very rapid advances which have occurred in recombinant DNA technology, which allows the sequencing of the genetic make up of individuals. There are two main branches of laboratory genetics: clinical cytogenetics, which involves the microscopic analysis of chromosomal abnormalities; and molecular genetics, which uses the tools of DNA technology to analyse mutations (changes) in genes. Whilst the development around the human genome has been high-tech and painstaking, the resultant testing is likely to be highly automated and attractive/valuable to both doctors and the community. It is the area with the highest potential for a demand blow-out and one that is going to be problematic more at the medicine/community interface rather than in the laboratory. The tests arising from our understanding of the human genome will be very highly automated.
- **Forensic Pathology**, which is the subspecialty of pathology that focuses on medico-legal investigations of sudden or unexpected death. This is a state responsibility and only in regional areas would a local pathologist play a role. The tools of analysis may well be high-tech, but each investigation is unique and not automated. Where a local pathologist provides forensic services he/she may well use the medical laboratory technology and staff to undertake the investigations, but not at the expense of Medicare.

### 3.2 MBS Expenditure and Services

Since 1984, which is the entire period of funding pathology under Medicare, outlays have increased from \$346 million to just over \$2 billion, a 5.8 fold increase at an annual average growth of 7.3%. The first ten years had an average annual growth rate of 8.2% despite fee reductions of 13.2% in August 1986 and 8% in February 1992. The most recent ten years produced an average annual growth rate of 6.3% and the last three years of 3.6%. The most recent year 2009/2010 produced only a 2.1% increase in outlays, the effect of a half year impact of a net 5% fee cut in November 2009 and a reduction in the growth of demand. This financial year may well produce a growth in outlays of less than 2% if current demand levels are maintained. It is difficult to predict whether the current historically low growth rate will continue, as the causes are not established. However, the sector expects that demand will most likely return to higher levels.

There were three separate Memoranda of Understanding (MoU) with industry, covering the period from 1 July 1994 to 30 June 2009. The elimination of annual fee indexation under these MoU led to growth in outlays being primarily driven by increased service demand.

**Chart 1: Annual Medicare Outlays<sup>2</sup>**



Current expenditure for pathology is more than \$2 billion per annum.

**Table 2: Pathology Expenditure and Services – 2007/08 to 2009/10<sup>3</sup>**

Year	Services <sup>4</sup>	Benefits
2009/10	103.7 million	\$2.013 billion
2008/09	100.4 million	\$1.972 billion
2007/08	95.75 million	\$1.876 billion

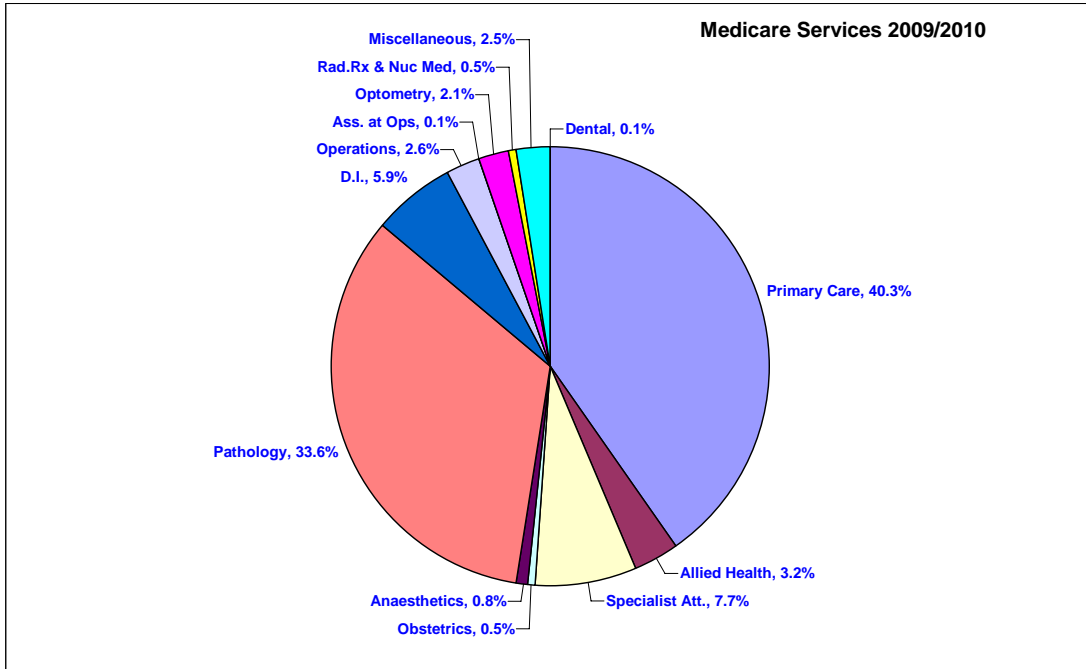
<sup>2</sup> MBS data

<sup>3</sup> MBS data

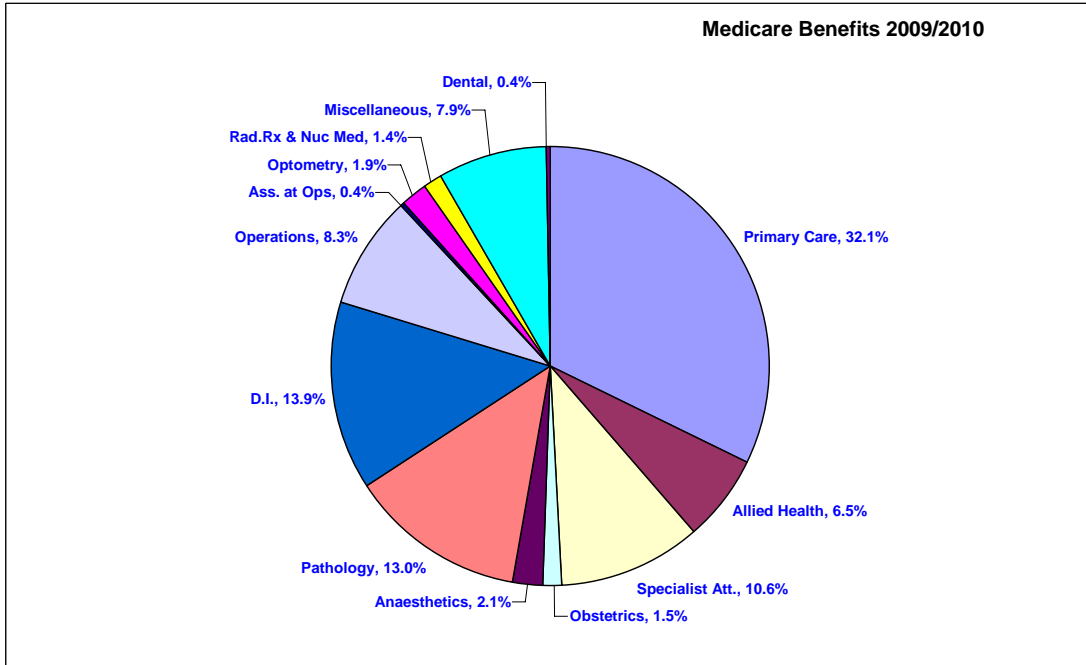
<sup>4</sup> All pathology services, including PEIs

In 2009/10, pathology represented 33.6% of total Medicare services, corresponding to 13% of total Medicare outlays. This disparity is a product of the micro-itemisation of pathology services in the MBS, with collection and analysis of a single patient specimen resulting in at least two rebatable services and often more.

**Chart 3: Pathology as proportion of Medicare Services<sup>5</sup>**



**Chart 4: Pathology as proportion of Medicare Benefits<sup>6</sup>**



<sup>5</sup> MBS data

<sup>6</sup> MBS data

## International Expenditure

In 2010, PricewaterhouseCoopers (PwC) was engaged to review international pathology funding arrangements, and they reported on arrangements in England, Germany, United States, New Zealand, Switzerland and Canada<sup>7</sup>. These jurisdictions were selected on the grounds that they face a number of similar economic and social challenges and yet represent a range of different healthcare models. It was found that all the jurisdictions face similar challenges in the delivery of high quality, accessible and affordable pathology services. Increasing prevalence of certain diseases has placed significant pressures on health care budgets across the world. All the jurisdictions have therefore been focussing on mechanisms to increase efficiency in health services while not compromising the quality of services.

The table below shows that Australia pays less per capita for pathology than all other countries except for New Zealand and the UK. While this is considered a reasonable indicator, it needs to be stated that comparisons between countries are undertaken without using the same parameters, i.e. the same cohort of patients, the same types of tests, overall population etc.

**Table 5: Expenditure per Capita (USD, 2000, PPP)<sup>8</sup>**

	<b>Aus</b>	<b>Can</b>	<b>Germ</b>	<b>NZ</b>	<b>Switz</b>	<b>UK</b>	<b>US</b>
<b>Public</b>	1,829	2,185	2,223	1,724	2,147	2,036	2,684
<b>Private</b>	872	945	671	487	1,485	446	3,258
<b>Total per capita</b>	2,701	3,130	2,894	2,211	3,632	2,482	5,942

### Growth in demand

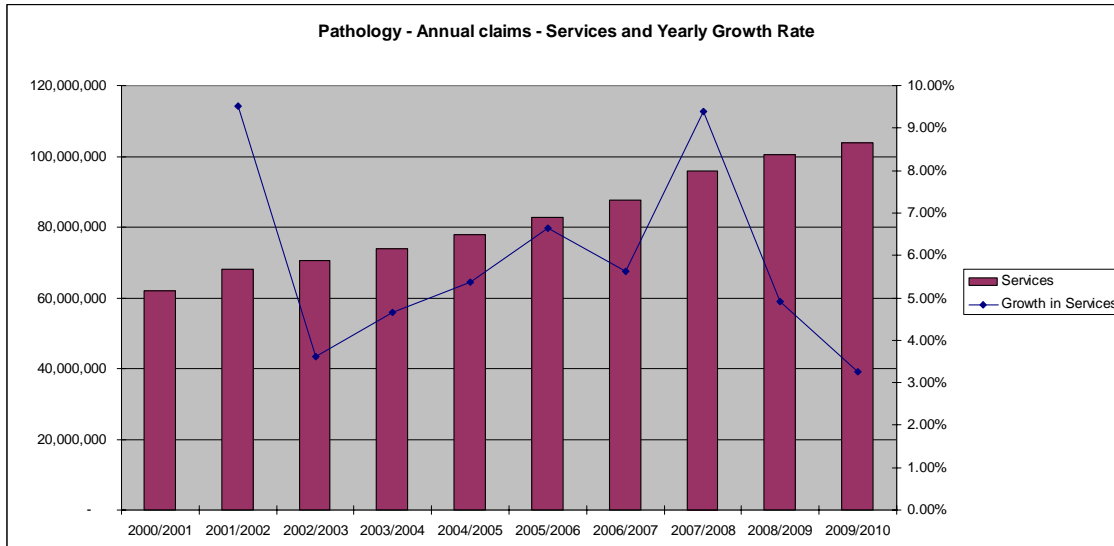
Since 1993/94, the number of pathology services provided each year has grown at an average rate of 5.7% per annum, with the growth of corresponding benefits paid of 6.8% per annum. But, the last year shows a reduction in growth of demand and a reduction in the growth of outlays.

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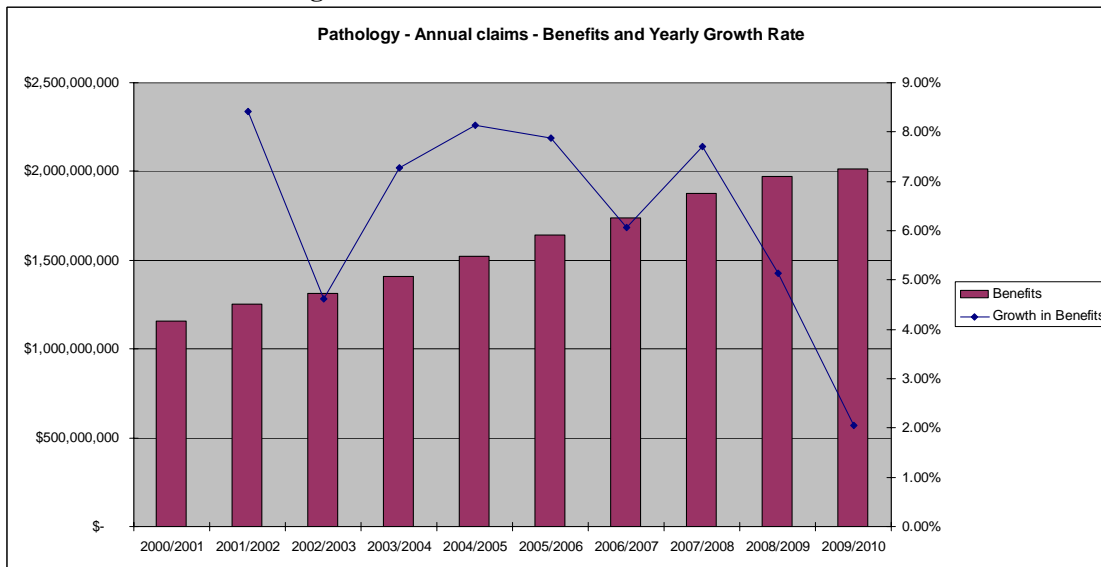
<sup>7</sup> PricewaterhouseCoopers, *International Review of Pathology Funding Arrangements*, March 2010  
[http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRTG-Pathology\\_Publications](http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRTG-Pathology_Publications)

<sup>8</sup> Extract from Appendix A of PwC report

**Chart 6: Annual Average Growth in Services<sup>9</sup>**



**Chart 7: Annual Average Growth in Benefits<sup>10</sup>**

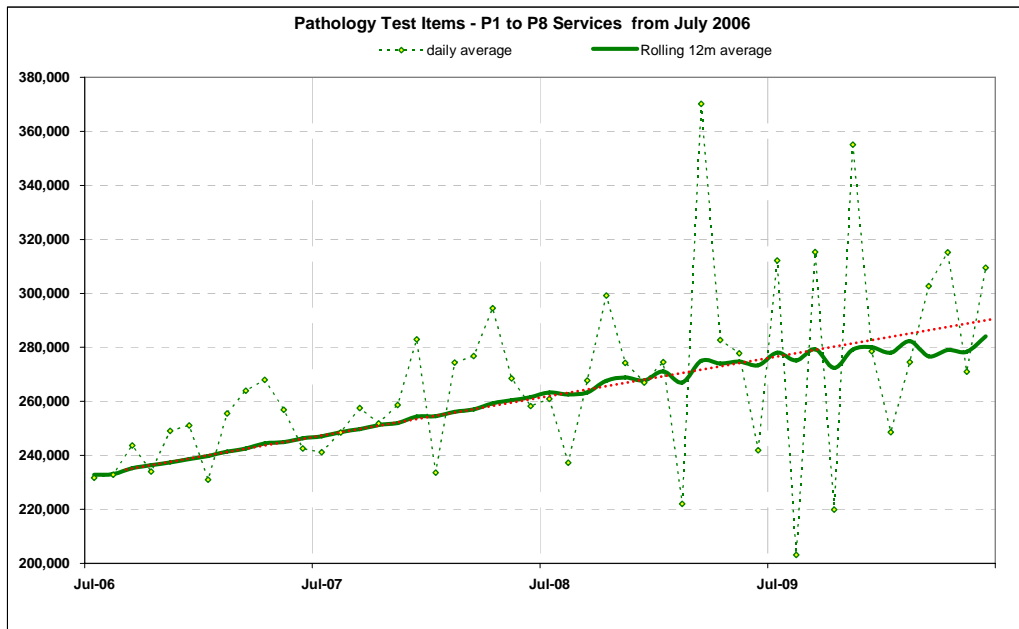


Over the last financial year (2008-09 to 2009-10), the steady growth in demand has plateaued and growth in services is 3.3%.

<sup>9</sup> MBS data

<sup>10</sup> MBS data

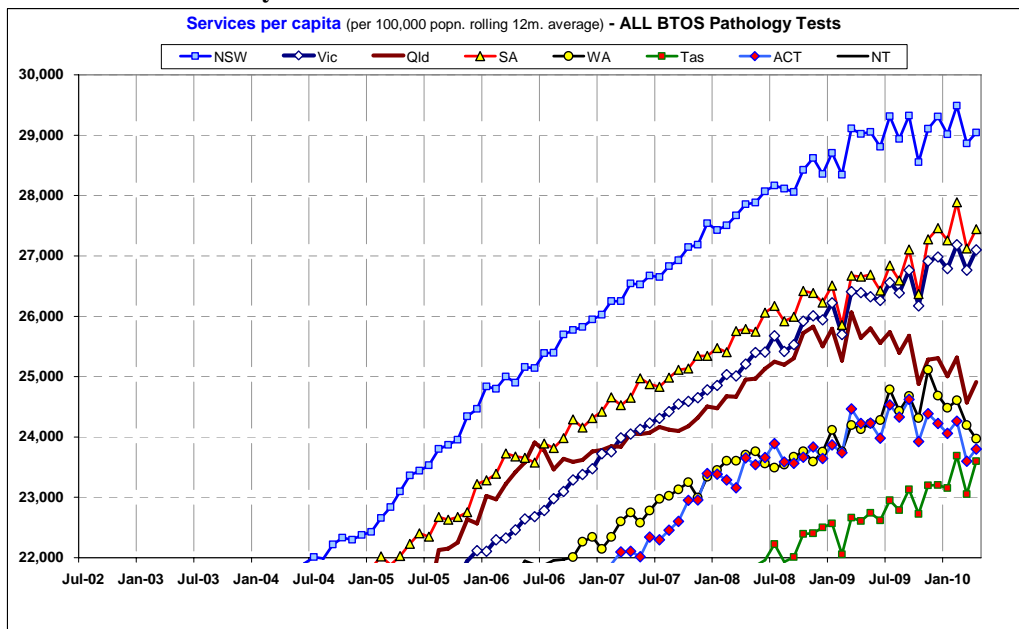
**Chart 8: Growth in Demand<sup>11</sup>**



NB. Recent data inconsistencies are the product of a change in Medicare Australia's claims processing.

The national downturn in growth is the result of different trends in each state. States still in apparent growth include South Australia and Tasmania whilst NSW and Victoria appear to have plateaued and ACT, Western Australia and particularly Queensland are in decline.

**Chart 9: Services by State<sup>12</sup>**



**Distribution of pathology services by discipline**

Pathology services are distributed unevenly across each of the P Groups within the PST. The distribution of expenditure against each P group indicates that P1 – Chemical Pathology, has the highest proportion of expenditure (39.2%), followed by P2 – Microbiology (14.2%). Expenditure

<sup>11</sup> MBS data

<sup>12</sup> MBS data

for P7 – Genetics, represents 1.2% of total expenditure, whereas P10 - Patient Episode Initiation (PEI), which was established to provide a contribution towards the cost of pathology collections, represents 12.3% of total expenditure. The reduced share of benefits for P10 and increased share for P5 in 2009/10 is the result of fee adjustments made in the 2009/10 Budget.

**Table 10: Distribution of Pathology Expenditure by financial year 2007-08 to 2009-10<sup>13</sup>**

**Distribution of MBS pathology expenditure by Financial year 2007-08 to 2009-10**

<i>P group</i>	2007-08		2008-09		2009-10	
	Benefits paid (\$)	% of total benefits	Benefits paid (\$)	% of total benefits	Benefits paid (\$)	% of total benefits
<b>P1-Haematology</b>	235,121,059	12.5%	241,225,671	12.2%	246,151,702	12.2%
<b>P2-Chemical</b>	700,176,816	37.3%	738,145,104	37.4%	789,503,187	39.2%
<b>P3-Microbiology</b>	255,291,759	13.6%	278,023,748	14.1%	285,953,147	14.2%
<b>P4-Immunology</b>	75,341,383	4.0%	80,345,901	4.1%	85,029,158	4.2%
<b>P5-Tissue pathology</b>	198,064,011	10.6%	207,562,715	10.5%	224,381,778	11.1%
<b>P6-Cytology</b>	42,189,707	2.2%	42,775,534	2.2%	42,549,355	2.1%
<b>P7-Genetics</b>	20,538,574	1.1%	21,269,969	1.1%	23,931,889	1.2%
<b>P8-Pregnancy tests</b>	9,632,512	0.5%	10,601,680	0.5%	11,132,593	0.6%
<b>P9-Simple Basic tests</b>	4,606,859	0.2%	4,441,663	0.2%	4,263,116	0.2%
<b>P10-PEI</b>	329,199,130	17.5%	342,021,541	17.3%	246,612,633	12.3%
<b>P11-Specimen Referred</b>	3,771,153	0.2%	3,884,171	0.2%	3,945,373	0.2%
<b>P12-Management of bulk-billed services</b>	1,851,795	0.1%	1,789,414	0.1%	1,739,266	0.1%
<b>P13- Bulk-billed episode incentive</b>	-	0.0%	-	0.0%	47,495,419	2.4%
<b>Total Path (P1-P13)</b>	1,875,784,759	100.0%	1,972,087,110	100.0%	2,012,688,617	100.0%

### 3.3 Public and Private Sectors

Pathology services are available through both the public and the private sectors, however the sectors are very different, and some of the traditional boundaries between the sectors have become blurred in recent times. For example, some public hospital pathology services are now provided by the private sector, and some services provided to community patients are provided by the public sector.

#### Public Sector Pathology

Services provided through the public sector represent approximately 40% of pathology in Australia<sup>14</sup>. About 14.6% of MBS pathology services and 13.8% of total benefits paid were provided by the public sector in 2009/10<sup>15</sup>.

The majority of these services, which are not funded under MBS arrangements, are:

- Public hospital in-patient services, which are funded through public hospital funding arrangements. The quantum of services provided in public hospitals is unknown;
- Reference Laboratories, providing specialised pathology services such as the Victorian Cytology Services, which specialises in cervical cytology tests, and the Queensland

<sup>13</sup> MBS data

<sup>14</sup> Legg, M. *The Australian Pathology Workforce Crisis*, 2008. Pp5, Report funded by Quality Use of Pathology Program

<sup>15</sup> MBS data

Mycobacterium Reference Laboratory, which provides diagnostic and reference services in mycobacterial diseases (tuberculosis, atypical mycobacteriosis, Hansen's Disease) to public and private pathology laboratories in Queensland; or

- Other services, such as transplant services, neonatal screening, and the majority of genetic services. There is also a view from within the public sector, provided through responses to the first Discussion Paper, that the public sector provides a high proportion of less profitable, complex services which are referred to them by the private sector<sup>16, 17, 18</sup> although this is disputed by others within the private sector<sup>19</sup>.

Some public laboratories provide pathology for private in-patients of the public hospital and sometimes for private in-patients of a co-located private hospital. These services are funded through the MBS.

In some states, public pathology laboratories are also active in providing services for community, out-of-hospital patients, which are funded through the MBS. This occurs more frequently in rural and remote areas, where access to private facilities may be reduced, or to meet community service obligations

### **Private Sector Pathology**

Services provided through the private sector represent approximately 60% of pathology in Australia, primarily funded through MBS arrangements.

Private pathology services are dominated by three large corporate providers, Sonic Healthcare, Primary Health Care and Healthscope. The primary focus for the private sector is MBS-eligible services; both private hospital in-patients and community patients. Other sources of revenue include employee drug and alcohol testing, compensation work and veterinary pathology.

### **3.4 Niche/Boutique Laboratories versus Comprehensive Laboratories**

There are fundamentally two different types of laboratories; comprehensive laboratories, that provide a full range of pathology services; and those referred to as 'niche' or 'boutique' laboratories, that provide a specialised service for a subset of pathology services.

Stand-alone 'boutique' anatomical pathology providers appear to be flourishing, with 32 APAs in 2009/10 just claiming anatomical pathology services, and another 8 APAs just claiming anatomical pathology and cytology (group P6) – up from 26 and 7 respectively in 2007/08 – out of a total of 197 APAs.

Despite some growth in boutique anatomical pathology laboratories, most pathology in Australia is provided in comprehensive laboratories that provide a wide range of testing services at a single location. This allows for the efficient use of workforce and technology, as well as the generation of economies of scale in courier networks for the delivery of specimens and reports.

### **3.5 Quality in Pathology**

Australia's pathology system is highly regarded for its quality service provision. The high quality is

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<sup>16</sup> QLD Health, Submission to the first Discussion Paper, May 2010

<sup>17</sup> NCOPP, Submission to the first Discussion Paper, May 2010

<sup>18</sup> Vic Health, Submission to the first Discussion Paper, May 2010

<sup>19</sup> AAPP, Submission to the first Discussion Paper, May 2010



a result of the accreditation system in place.

In 1986, the Commonwealth introduced a compulsory accreditation system in relation to Medicare benefits for pathology. In order to be accredited, a pathology laboratory must meet specified quality standards. The National Pathology Accreditation Advisory Council (NPAAC) is responsible for developing and maintaining standards and guidelines for pathology laboratories. Audits against these standards and guidelines are conducted by the National Association of Testing Authorities, Australia (NATA), with support from the RCPA. These audit assessment reports are considered by Medicare Australia in determining eligibility to access the Medicare Benefits Schedule.

In addition to the NPAAC/NATA arrangements, the RCPA Quality Assurance Program also supports quality and safety in pathology laboratories by providing a broad range of external quality assurance programs across all disciplines of pathology.

Whilst there is confidence that quality and safety within laboratories is very high, there is room for improvement at the stages of specimen collection and reporting of results. It is difficult for pathology laboratories to be sure that their reports have been read, understood and acted upon by the requesting doctor. Waste can also occur if specimens are incorrectly identified at collection, as repeat testing is likely. Work undertaken as part of the RCPA Quality Assurance Program suggests that misidentification may affect up to 1% of pathology specimens. In addition, a recent Quality Use of Pathology Program project undertaken by the Consumers Health Forum<sup>20</sup> recommended the credentialing of the people who collect samples at collection centres. This was based on the report's findings that the adequacy of training given to pathology collection centre staff was a concern and they noted distinct differences in the skills of private pathology collection staff when compared to public sector collection staff.

There are currently NPAAC guidelines for the operation of collection centres which refer to staff training, but the training requirements are not specified. There are TAFE courses for specimen collection, typically around 6 weeks in duration, and many laboratories train their own staff independently of these courses.

### **3.6 The Role of Pathology in Clinical Practice**

Both general practitioners (GPs) and medical specialists are able to request pathology services under MBS arrangements.

#### **General Practitioner Requesting**

Pathology is essential for GPs for diagnosing, monitoring and managing their patients.

A study of the impact of the use of general practice computer systems on the ordering of pathology<sup>21</sup> identified a number of factors that influence GPs in their order of pathology, including:

- Clinical decision-making factors - Medical diagnoses;
- Patient management factors - Follow-up, screening, prevention, pre-operative, pre-referral, to buy time/delaying tactic, opportunistic/patient convenience;

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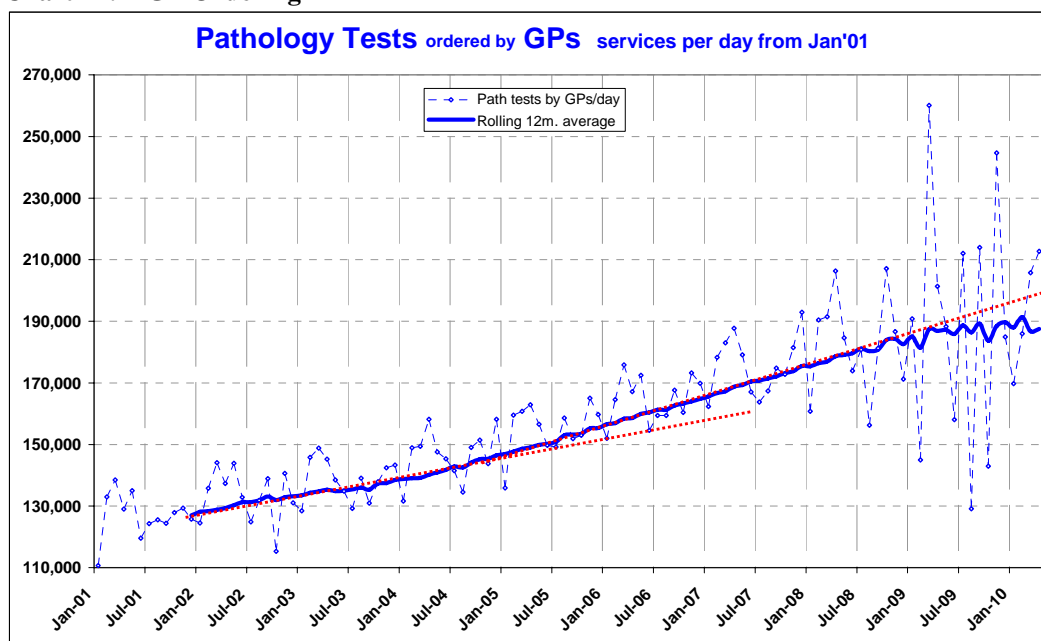
<sup>20</sup> *Pathology Consumer Consultation* project by the Consumers Health Forum 2010, funded by the Quality Use of Pathology Program.

<sup>21</sup> *A study of the impact of the use of general practice computer systems on the ordering of pathology* – Michael Legg & Associates, IRIS Research, the University of Wollongong and Dr Ian Cheong – May 2004 funded by the Quality Use of Pathology Program.

- Patient-driven factors - Patient request/demand, consumerism;
- Style of practice - Some order more tests if they spend more time and are being thorough, conversely others spend less time with patients and order more tests in lieu;
- Business or marketing factors for GP practices - Maintaining patient satisfaction, patient perception that a good doctor orders pathology, patients like printed information;
- Economic and bureaucracy factors - Doctors and patients are generally unaware of the cost of pathology tests; and
- Medico-legal factors - Defensive medicine, fear of failure to diagnose conditions.

Over the last decade, GP pathology requesting has steadily increased. Growth now however appears to be increasing at a much lesser rate, with the current rate of growth being only 0.4% in the last year.

**Chart 11: GP Ordering<sup>22</sup>**



While MBS data indicates a constant growth in GP pathology requests, the quantum of actual tests ordered by GPs is unknown due to the limitations of data resulting from the episode cone.

### Episode Coning

The ‘episode cone’ describes an arrangement under which, in a patient episode for a set of pathology services of more than three items, the Medicare benefits payable will be equivalent to the sum of the benefits for only the three items with the highest Schedule fees. It applies only to non-inpatient services requested by GPs. The episode cone does not apply to inpatient services, or for services requested by medical specialists.

The episode cone was introduced in the mid-1990s as part of a strategy to address concerns about the exploitation of the MBS through the inducement of requests for unnecessary tests and minimise the impact of high content referrals. High content referrals are disproportionately profitable as successive items increasingly relate to the marginal cost of testing. The introduction of the episode cone was expected to provide an incentive to discourage high content referrals. Pathology providers had a financial incentive to communicate with their referrers and encourage logical,

<sup>22</sup> MBS data

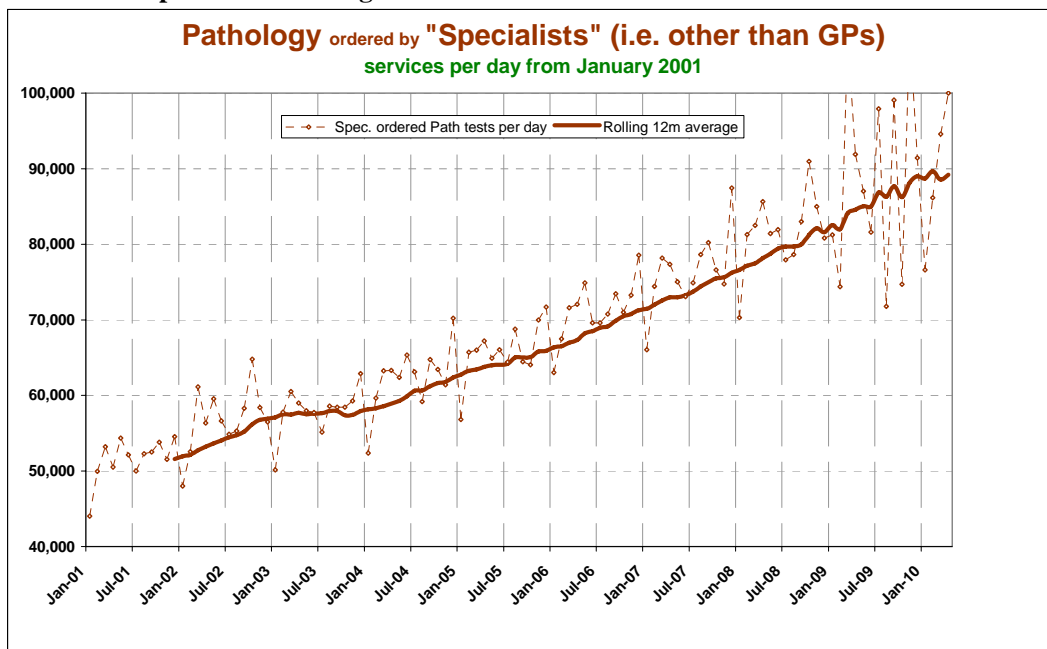
sequential and hierarchical investigations instead of scatter-gun pathology requesting, as the pathology practices would bear the cost of the fourth and subsequent tests. It was accepted by the profession as a saving made against inappropriate practice with little impact on the incomes of orthodox practices.

As indicated above, a consequence of the episode cone is that the full range of services requested by the GP is not available to the government. Pathology billing software now processes episode coning prior to the lodgement of the accounts with Medicare Australia for processing, as this is more efficient in terms of accounting and claims reconciliation. This means that ‘unconed’ services do not leave a footprint in the system, and the complete GP request is known only to the pathology sector.

### Specialist Requesting

The rate of growth in pathology ordering by specialists has shown relatively constant growth, at 5.5% for the last year.

**Chart 12: Specialist Ordering**<sup>23</sup>



### Differences between GP and Specialist Requesting

While specialists are responsible for a smaller proportion of pathology volumes than GPs, per 100 consultations they order approximately 50% more tests than GPs, with those tests representing an average additional expenditure of approximately \$4 per service, which has remained constant over time.

GPs and specialists both provide a diverse range of services to their patients, and are difficult to compare. Specialists’ orders have higher test numbers and are more expensive, partly because the episode cone does not apply and also because specialists are more likely to request more expensive esoteric tests. They do not undertake as many consultations as GPs and are more targeted in their requesting.

GP requests reflect the fact that they can have high degrees of uncertainty about the possible cause

<sup>23</sup> MBS data

of a patient's symptoms. A portion of GP requesting is not captured due to the episode cone, making accurate comparisons is difficult.

A patient contribution is more likely to be sought if a pathology service is requested by a specialist, than if it is requested by a GP, and co-payments are most commonly sought for P5 - Tissue Pathology.

**Table 13: Pathology data by requesting provider<sup>24</sup>**

Pathology - Patient contribution, by P group, requesting provider type  
Period: FYs 2007-08, 2008-09, 2009-10

FY	Requesting providers type	Patient contribution (\$)													Total Pathology
		P1- Haematology	P2- Chemical	P3- Microbiology	P4- Immunology	P5-Tissue pathology	P6- Cytology	P7- Genetics	P8- Pregnancy tests	P9-Simple Basic tests	P10-PEI	P11- Specimen Referred	P1-P8		
2007/08	GP	3,170,049	6,997,143	1,987,021	130,135	887,983	882,394	57,045	287,762	315,985	4,996,100	62,908	14,024,802	19,402,575	
	Specialist	21,081,014	28,619,943	9,242,284	3,161,901	44,484,170	2,718,712	2,101,808	1,108,417	47,242	17,546,818	239,388	110,513,128	123,350,574	
<b>Total</b>		<b>24,251,063</b>	<b>33,616,986</b>	<b>11,229,285</b>	<b>3,031,766</b>	<b>45,372,163</b>	<b>3,601,105</b>	<b>2,044,163</b>	<b>1,396,209</b>	<b>363,206</b>	<b>22,547,918</b>	<b>299,295</b>	<b>124,542,730</b>	<b>147,753,149</b>	
2008/09	GP	3,413,237	7,986,940	2,261,815	82,909	1,091,425	885,817	32,963	359,429	314,958	6,888,431	68,584	15,802,561	21,874,563	
	Specialist	22,781,982	28,416,255	10,164,031	3,625,696	48,210,899	2,986,339	2,370,844	1,388,375	58,488	19,420,061	241,311	119,844,420	139,564,281	
<b>Total</b>		<b>26,195,219</b>	<b>36,383,195</b>	<b>12,365,646</b>	<b>3,442,787</b>	<b>49,302,324</b>	<b>3,872,156</b>	<b>2,337,882</b>	<b>1,747,803</b>	<b>373,446</b>	<b>25,108,493</b>	<b>309,895</b>	<b>135,647,011</b>	<b>161,438,844</b>	
2009/10	GP	5,488,708	15,696,441	5,531,579	288,248	1,876,494	1,546,716	14,528	535,838	301,238	10,568,788	60,228	30,930,296	41,880,550	
	Specialist	26,656,704	33,875,527	11,910,800	4,036,875	57,947,348	3,535,609	2,441,124	1,719,878	60,106	22,214,485	193,590	142,022,464	164,460,645	
<b>Total</b>		<b>32,042,412</b>	<b>49,571,968</b>	<b>17,442,379</b>	<b>4,322,922</b>	<b>59,823,842</b>	<b>5,085,324</b>	<b>2,426,596</b>	<b>2,255,316</b>	<b>361,344</b>	<b>32,783,273</b>	<b>253,818</b>	<b>172,952,760</b>	<b>206,351,195</b>	

FY	Requesting providers type	% of Benefits paid by requesting provider's peer group													Total Pathology
		P1- Haematology	P2- Chemical	P3- Microbiology	P4- Immunology	P5-Tissue pathology	P6- Cytology	P7- Genetics	P8- Pregnancy tests	P9-Simple Basic tests	P10-PEI	P11- Specimen Referred	P1-P8		
2007/08	GP	13.1%	20.8%	17.7%	-4.3%	2.0%	24.5%	-2.8%	20.6%	67.0%	22.2%	21.0%	11.3%	13.1%	
	Specialist	86.0%	79.2%	82.3%	104.3%	98.0%	75.5%	102.8%	79.4%	13.0%	77.8%	79.0%	88.7%	86.9%	
<b>Total</b>		<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	
2008/09	GP	13.0%	21.9%	17.8%	-2.4%	2.2%	22.9%	-1.4%	20.6%	64.3%	22.7%	23.1%	11.9%	13.5%	
	Specialist	87.0%	78.1%	82.2%	102.4%	97.8%	77.1%	101.4%	79.4%	15.7%	77.3%	77.9%	88.4%	86.5%	
<b>Total</b>		<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	
2009/10	GP	17.1%	31.7%	31.7%	6.6%	3.1%	30.5%	-0.6%	23.8%	83.4%	32.2%	23.7%	17.9%	20.3%	
	Specialist	82.9%	68.3%	68.3%	93.4%	96.9%	69.5%	100.6%	76.2%	16.6%	67.8%	76.3%	82.1%	79.7%	
<b>Total</b>		<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	

## Nature of Growth in Pathology

As previous indicated, pathology usage is determined by factors that influence doctors on an individual level, as well as state-based nuances. The variations in growth between states are demonstrated below:

**Table 14: State Variances in Pathology Growth for 2009/10<sup>25</sup>**

Test Items (P1 to P8 inc.) – Growth Rates 2009-2010									
	NSW	Vic	Qld	SA	WA	Tas	ACT	NT	Aus
<b>Services</b>	3.6%	6.1%	-0.3%	6.0%	3.7%	5.4%	2.9%	2.1%	<b>3.6%</b>
<b>Benefits</b>	5.7%	8.2%	0.9%	8.3%	5.3%	8.5%	4.2%	2.7%	<b>5.5%</b>
<b>All Pathology Benefits</b>	2.8%	3.9%	-2.7%	5.9%	2.0%	4.6%	1.1%	0.6%	<b>2.1%</b>

There are also a number of additional elements that impact the rate of growth of pathology:

### *Inherent uncertainty around pathology results*

Patients and requesting doctors who are not pathology specialists tend to assume that pathology results are completely accurate. Pathology laboratories in Australia are subject to stringent accreditation requirements, including participation in external quality assurance programs designed to identify any systematic errors in their results. Despite this, there is an unavoidable level of inherent uncertainty in pathology results, even when they are reported as numerical measurements. As a result, doctors may misinterpret a patient's pathology results. For example, just because the

<sup>24</sup> MBS data

<sup>25</sup> MBS data

reported measurement of a particular substance has changed, this does not necessarily mean that the patient's levels of that substance have changed - the difference in the report may be the result of other factors, including the inherent uncertainty of the measurement technique used. Patients are unlikely to appreciate this distinction and may become concerned if their pathology result appears to have changed but their doctor does not take action<sup>26</sup>.

One way that doctors decide whether a pathology result requires clinical action is to compare it to a reference range, which is the average range of results from a relevant healthy population and may be specified by age, gender or other characteristics. This may be an accepted range, or may be specific to particular laboratories. For some biomarkers, target levels have been established, which are used instead of reference ranges. However, it is normally calculated to reflect the results for 95% of health individuals and therefore it would be expected that around 5% of pathology results for healthy patients will return a result outside the reference range.<sup>27</sup> As a result, unless the doctor has reason to suspect that there may be disease present that pathology testing can confirm or refute, requesting pathology can result in unnecessary clinical action and further testing that will not help, and may well harm, the patient.

Vitamin D testing is a good example of this, whereby, in Australia, a variety of assays are used to measure 25-OHD. Considerable variability however exists among the various assays available and among laboratories that conduct the analysis. Given the potential impact upon treatment, 25-OHD tests could include a statement of measurement uncertainty.

### 3.7 The Patient Perspective

According to the ABS survey, *Health Services: Patient Experiences in Australia, 2009*<sup>28</sup>, almost half of people aged 15 years and over (49% or 8.4 million people) had a pathology test sometime in the year prior to the survey. Across the States and Territories, the pathology testing rate was highest in Tasmania (53%) and lowest in the NT at 44%. Women were more likely to have had diagnostic testing than men (55% of women compared with 42% of men for pathology tests). Women up to age 55 were much more likely to have had these tests.

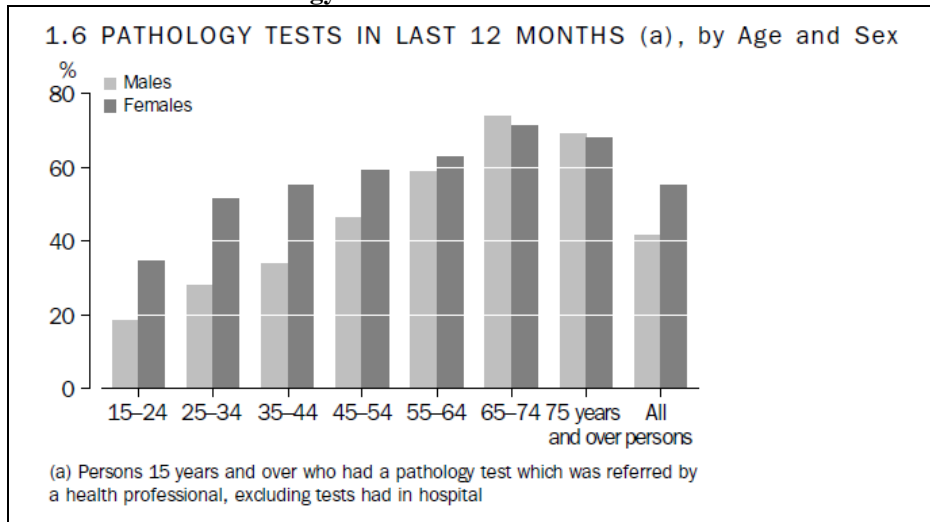
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<sup>26</sup> National Pathology Accreditation Advisory Council (NPAAC), *Requirements for the estimation of measurement uncertainty*, 2007. Accessed 11 October 2010: <http://www.health.gov.au/internet/main/publishing.nsf/Content/npaac-emu-toc~npaac-emu-prin~npaac-emu-sources>

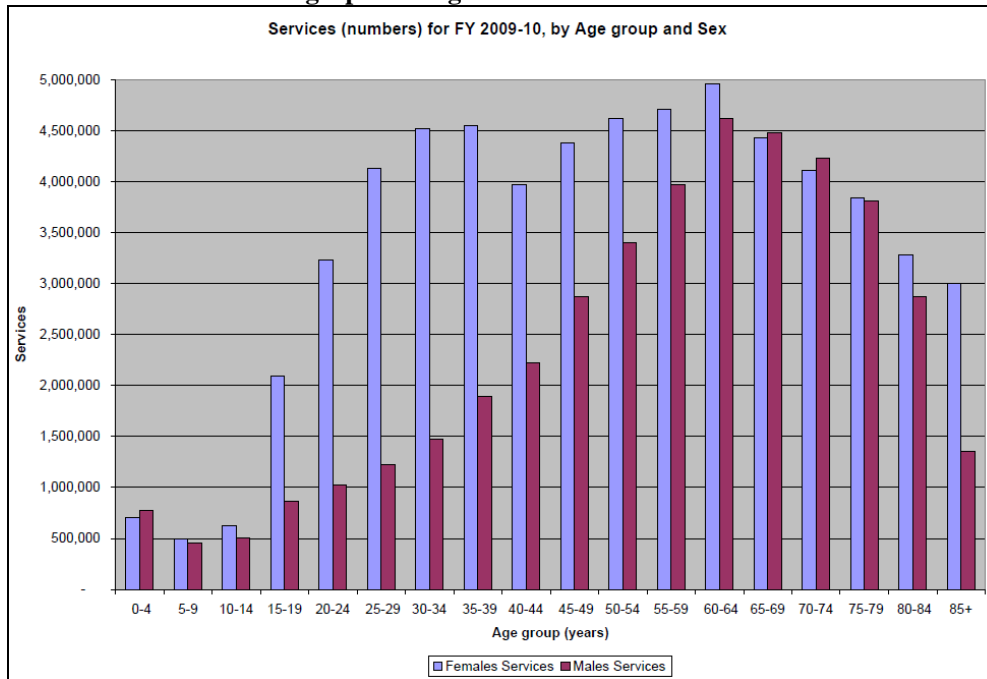
<sup>27</sup> Lab Tests Online (2010) *Reference ranges and what they mean*. Accessed 11 October 2010: [http://labtestsonline.org.au/understanding/features/ref\\_ranges.html](http://labtestsonline.org.au/understanding/features/ref_ranges.html)

<sup>28</sup> <http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/4839.0.55.0012009>

**Chart 15: ABS- Pathology tests in last 12 months<sup>29</sup>**



**Chart 16: Patient demographics – age sex<sup>30</sup>**



The ABS reported that of those patients who had a pathology test, 70.4% lived in major cities, 19.5% lived in inner regional areas, and 10% lived in outer regional/remote areas. 78.9% of these patients self-reported as being in good health and in terms of relative socio-economic disadvantage, 6.8% were most disadvantaged and 22.2% were least disadvantaged.

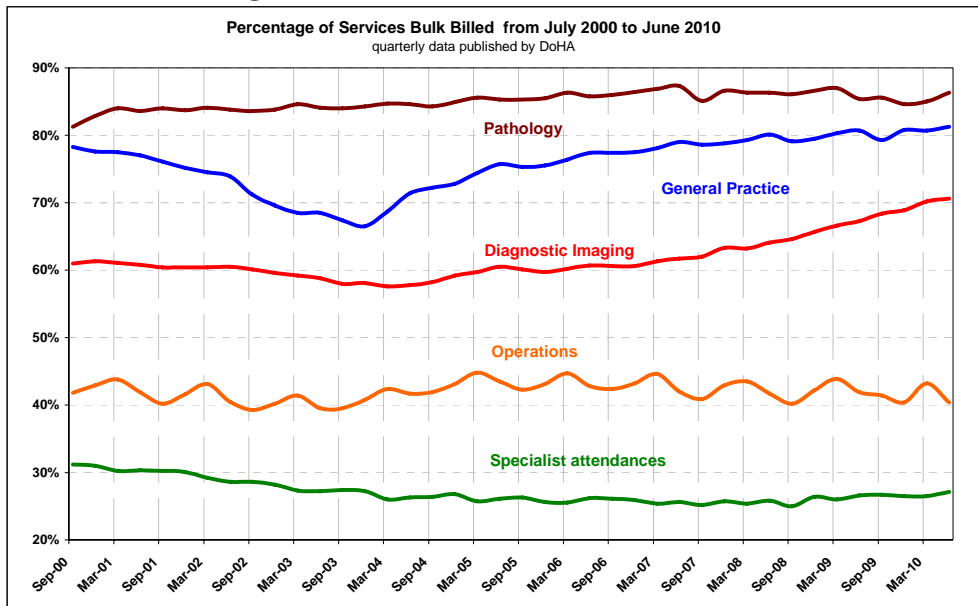
### Affordability of Pathology

Affordability of pathology remains high, as pathology services constantly remains the highest service type that is bulk-billed.

<sup>29</sup> ABS, 4839.0.55.001 - Health Services: Patient Experiences in Australia, 2009

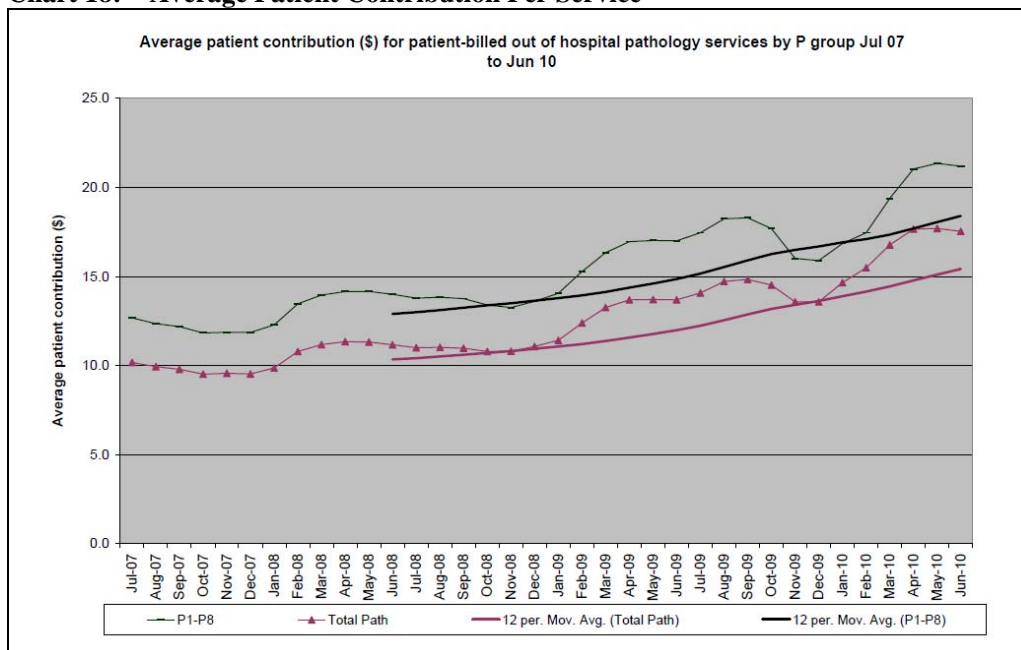
<sup>30</sup> MBS data

**Chart 17: Percentage of Services Bulk-Billed<sup>31</sup>**



While out-of-pocket expenses for patients have increased from an average of around \$10 per service to just over \$15 per service over the last few years, out-of-pocket expenses remain low compared to other MBS services.

**Chart 18: Average Patient Contribution Per Service<sup>32</sup>**



The *Health Services: Patient Experiences in Australia, 2009* ABS survey however identified cost as a barrier to pathology tests for some Australians. Their research showed that 281,400 people (less than 2% of people aged 15 years or over) delayed having or did not have a pathology test in the past year because of the cost. Slightly more women than men found cost a barrier to pathology tests. However, this was much lower than for other medical services, with 17% of patients indicating they had not seen a GP and 20% that they had not seen a specialist due to cost.

<sup>31</sup> MBS data

<sup>32</sup> MBS data

While co-payments are more likely to be sought for a service requested by a specialist than a GP, the following table shows that co-payments have increased for both in the last financial year, with a higher rate of growth for GPs, as shown in the Table below.

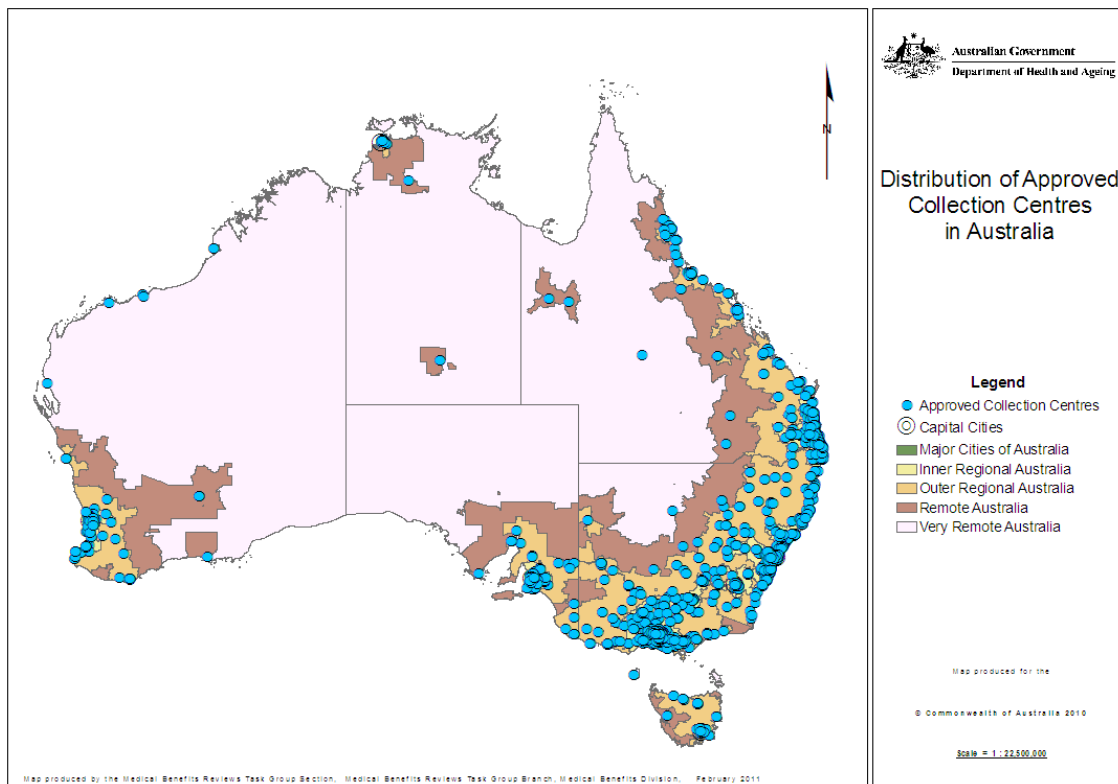
**Table 19: Patient Contribution by Provider Type<sup>33</sup>**

<i>Financial Year</i>	<i>Requesting provider type</i>	<i>\$ Total Pathology</i>	<i>% Total Pathology</i>
2007/08	GP	19,402,575	13.1%
	Specialist	128,350,574	86.9%
<b>Total</b>		<b>147,753,149</b>	<b>100.0%</b>
2008/09	GP	21,874,563	13.5%
	Specialist	139,564,281	86.5%
<b>Total</b>		<b>161,438,844</b>	<b>100.0%</b>
2009/10	GP	41,860,550	20.3%
	Specialist	164,490,645	79.7%
<b>Total</b>		<b>206,351,195</b>	<b>100.0%</b>

### Availability of Pathology

The distribution of ACCs is currently well aligned with the Australian population, with 3,584 ACCs nation-wide (at 5 November 2010).

**Diagram 20: Distribution of Collection Centres<sup>34</sup>**



<sup>33</sup> MBS data

<sup>34</sup> Medicare and MBS data



## Patient Understanding and Satisfaction

The ABS survey found that, as with reasons for the test, pathology results were well understood, although slightly less so than the reasons were. Results were understood completely by 90% of people and understood to some extent by a further 10%.

Satisfaction with arrangements for receiving results of the most recent pathology test was generally high, with 51% of people very satisfied and a further 39% satisfied. Only 6% of people said that they were either dissatisfied or very dissatisfied.

## Patient Concerns

The Consumer Health Forum of Australia, through its report *Quality Use of Pathology Consumer Consultation Project- June 2010*<sup>35</sup>, identified that issues of access and availability of testing facilities for consumers who live in rural and remote areas of Australia is a key issue. For high end users of pathology, living in a remote or rural region can present unique challenges both in terms of reaching a facility to have their tests done and then the time which it may take for their tests to be analysed and for them to eventually receive their results. A lack of choice is a significant issue for consumers living in regional/remote areas. They are often forced to go long distances or to a single provider simply because there is no other option. Further to this, consumers have identified the restricted availability of some testing as another concern. Not all tests are available at their nearest collection point, which is a particular concern when testing for complicated or rare conditions.

There do not appear to be significant differences in copayments between metropolitan, rural and remote areas.

**Table 21: Patient contributions by location**<sup>36</sup>

<b>Location</b>	<b>Total Services (Patient-billed, Out-of-Hospital)</b>	<b>Total Patient Contribution (\$) (Patient-billed, Out-of-Hospital)</b>	<b>Average patient contribution (\$)</b>
Capital City	3,268,943	50,145,309.58	15.34
Other Metro Centre	461,803	7,114,182.56	15.41
Large Rural Centre	426,006	6,198,602.12	14.55
Small Rural Centre	313,778	4,786,834.50	15.26
Other Rural	629,263	9,628,093.59	15.30
Remote Centre	48,606	667,753.48	13.74
Other Remote Area	48,737	655,269.72	13.45

## 3.8 The Funding System

### Regulatory Arrangements

Current pathology arrangements consist of: overarching Approved Pathology Authorities (APA); ACCs; Accredited Pathology Laboratories (APL); and Approved Pathology Practitioners (APP), as well as other staff.

<sup>35</sup> Consumers Health Forum *Quality Use of Pathology Consumer Consultation Project- June 2010* Report: <https://www.chf.org.au/pdfs/chf/CHF%20Final%20Quality%20Use%20of%20Pathology%20Report.pdf> Accessed 28 September 2010

<sup>36</sup> MBS data

APAs are accountable for all pathology services. APAs can range from state governments or large corporate entities, through to individual pathologists (who can also be an APP). An APA is required to have control over: the laboratory premises; the use of the equipment used in the lab; and the employment of staff in the lab. APAs sign an undertaking that they provide, including compliance, accountability, ongoing financial assurance, inspection of premises, quality assurance, arrangements with the APP, and accounts.

ACCs are established by APAs to collect specimens from patients. This is the element that impacts access for patients, and the element that drives competition between APAs. The number of ACCs available to each APA was, until recently, determined via a formula. However, restrictions were removed on 1 July 2010, allowing competitive market factors to determine the need for collection centres.

APLs are controlled by APAs and must be accredited through NATA for the services they provide, to be eligible for Medicare rebates.

APPs are most commonly pathologists, but a GP who undertakes pathology tests can also be an APP. APPs must be employed by or contracted to an APA. An APP can also be an APA (proprietor) in the case of independent providers. Through a signed undertaking, the APP accepts responsibility for all pathology services that are provided by, or on behalf of them by other staff, by agreeing that they will ensure the person undertaking the service is properly supervised (but not necessarily qualified). A single APA can have one or more APPs working for them, and APPs are able to work for more than one APA.

Other staff can be pathologists that are not APPs in their own right, scientists, technicians, lab assistants, etc. The skills needed to perform the test(s) are determined by individual labs, and supervision is provided by the APP.

### **Pathology Services Table**

Pathology is primarily government funded through Medicare arrangements. The PST, which lists the services that attract a Medicare rebate, is a subset of the MBS.

Since 1984 there have been many changes to the structure of the PST with items being aggregated and others disaggregated and the introduction of entirely new groups of items which relate to referral rather than testing.

While the Rules of the PST have primarily been developed through or with oversight from the Pathology Services Table Committee (PSTC), which are discussed in more detail below, the approach has, over time, lead to current rules that are complex and difficult to follow.

### **Fee relativities**

Similar to other MBS items, the PSTC has historically established fees for pathology tests by aligning them with existing services of similar complexity. This approach has not facilitated adjustment over time where the cost of providing tests reduces, either as a result of new technology or as a result of increasing volumes allowing the generation of scale economies. To reduce the need for constant changes to the PST to reflect incremental technological change, the PSTC has had a policy of listing tests according to the analyte they measure, without regard for which method is used to generate the result. This allows laboratories to decide how to provide testing, with oversight through the accreditation system. This approach facilitates incremental technological change, including changes that increase efficiency, but makes more opaque what the MBS is paying for and whether the amount paid appropriately reflects costs. In common with other areas of the MBS,

pathology rebates generally do not vary to reflect other factors that affect costs, such as rurality and after-hours service provision.

The rate of technological change in pathology makes it difficult to make a judgement about which changes should be subject to formal health technology assessment of their efficacy and cost effectiveness. In addition, assessment of diagnostics is more complex, as their cost effectiveness is affected not only by their own features but also by the value of the treatment options they make available for the patient. For example, a pathology test for a disease may be extremely accurate, but if there is no treatment available for that disease then diagnosing it may be of little benefit for the patient.

### Funding of Genetics

Genetic testing is evolving rapidly, and now involves a sophisticated analysis of the components of individual genes. This has dramatically expanded the range of conditions and situations in which such tests may be of use. This in turn creates a major issue in deciding on the most appropriate methods of approving and publicly funding these tests. Responses to the advancements in genetics have been reactive rather than adaptive.

There are approximately 450 gene tests available in Australia<sup>37</sup>. About 74% of all genetic tests currently performed are funded by the States. A consultant to the pathology review has estimated that the States spend around \$34 million annually on genetic testing over and above that paid through the MBS. The 26% of tests funded by Medicare account for just 0.16% of total Medicare item expenditure.

The table below details genetics testing expenditure compared to overall MBS expenditure and overall pathology MBS expenditure.

**Table 22: Genetic funding as a percentage of Medicare expenditure<sup>38</sup>**

<b>2009/10 Type of Service</b>	<b>Services</b>	<b>%</b>	<b>Benefits</b>	<b>%</b>
All medical services	307,978,130	100.00%	\$15,413,726,090	100.00%
All pathology services	103,718,115	33.67%	\$ 2,012,688,616	13.05%
All genetic test services	153,188	0.05%	\$ 23,931,888	0.16%

#### *Approving New Genetic Tests for Funding*

New tests must go through the Medical Services Advisory Committee (MSAC) for inclusion on the MBS and this can be a slow process, and there is no mechanism for determining which tests should be prioritised for Medicare funding.

### Fee Indexation

Resulting from the MoU, discussed later in this paper, pathology is not subject to annual indexation that is applied to most other areas of the MBS. This is consistent with diagnostic imaging arrangements. However, it is apparent that industry has been able to find efficiencies through consolidation and automation to offset this.

<sup>37</sup> Australian Genetic Testing Survey 2006, G Suthers/RCPA, funded by the Quality Use of Pathology Program

<sup>38</sup> MBS data

## Public/Private Disparities

There are some disparities between funding of the public and private sectors that are worth discussion.

### *Patient Episode Initiation (PEI)*

PEIs were introduced for private sector pathologists in 1992 as a means of separating test costs from overhead costs such as specimen collection, storage, transportation, reporting and the raising of accounts. Public sector pathologists and public hospital laboratories were not given access to PEIs at this time. Since then there have been several amendments to the PEIs including the introduction of nominal PEIs for public laboratories in 2007.

The PEI fees are an ongoing issue within the pathology profession, mainly due to the significant financial differentials between the public and private pathology sectors.

It is now common practice for public laboratories to accept private work and to operate as independent business units that pay a hospital, state or territory for the infrastructure they use. Because of this, some in the pathology sector<sup>39</sup> argue that public and private providers should compete equally for pathology work and that MBS payments should not differentiate between private patients in public hospitals and private patients in other settings. Some stakeholders however believe that extending the PEI to include public pathology is in conflict with the original reasons for creating the PEI payments, that is to cover the expenses unique to private pathology practice. It is acknowledged that the former MoU with the pathology sector intended to move towards parity between the public and private sectors.

### *Competitive Neutrality*

Competitive neutrality policies aim to promote efficient competition between public and private businesses. Specifically, they seek to ensure that government businesses do not enjoy competitive advantages over their private sector competitors simply by virtue of their public sector ownership.

Applying competitive neutrality essentially requires making government business pricing decisions comparable with private sector organisations. This involves two steps, first, identifying all direct costs and, second, adding competitive neutrality components where necessary<sup>40</sup>.

- The first step is correctly identifying the direct costs of a function;
  - this is achieved by ensuring *accountability* and *transparency* of business operations. In all cases, the central principle is to identify all costs attributable to a business or activity.
- The second step involves identifying and adjusting for relevant costs or margins that apply in the private sector and which may not be fully accounted for in the direct costs to government, including:
  - achieving a *commercial rate of return* (ROR) on assets;
  - payment of all relevant Commonwealth and state *taxes*, or imposition of *Tax Equivalent Regimes* (TERs);
  - *regulatory neutrality* including, wherever possible, compliance with all relevant Commonwealth and state laws or regulations; and
  - *debt neutrality* including charges to account for implicit or explicit government

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<sup>39</sup> CHA submission to first Discussion Paper 18 May 2010 p8

<sup>40</sup> Commonwealth Competitive Neutrality Guidelines for Managers, 1998, pp7

guarantees on commercial or public loans.

The Department of the Treasury is responsible for policy on Commonwealth competitive neutrality<sup>41</sup> and provides Guidelines for Managers<sup>42</sup> on the principles and application of competitive neutrality.

Views provided by the sector through the submissions in response to the first Discussion Paper indicate that public/private differentials impact the pathology market. Public laboratory staff are salaried, and don't rely on income generated through services provided. It was noted that the current system allows for double dipping and that the public sector should have a transparent funding mechanism.

### **3.9 Economics of the Pathology Sector**

Pathology laboratories involve significant fixed costs, such as property, equipment and staff, which tend to rise or fall in steps. PricewaterhouseCoopers estimates that the minimum number of tests per day for a viable comprehensive laboratory would be around 5,000<sup>43</sup>. That is, the set up costs for a laboratory to provide a smaller number of tests per day would be too high to be covered by the revenue it could generate and therefore the laboratory is unlikely to be financially viable. Alternatively, a laboratory that reaches financial viability at 5,000 tests per day may be able to accommodate an additional number of tests, which incur direct costs, such as collection and reagent costs, but do not need to contribute to the fixed costs, which remain the same. That is, once a laboratory has sufficient throughput to cover its fixed costs, every additional test provided makes a greater contribution to profit. Pathology providers therefore compete fiercely for additional volume and market share.

#### *Economies of Scale*

Pathology laboratories have two kinds of economies of scale. One kind of scale economy relates to collection costs. The cost of collecting specimens, transporting them to the laboratory and entering them into the IT system is significant. However, these costs are only incurred once per specimen - once the specimen has been collected and transported, the cost of running additional testing is minimal. Current funding arrangements have sought to reflect this economy by paying for some costs on a per specimen collection basis, through the PEI, as well as through coning, which pays nothing for GP requested tests after the first three items. However, these current approaches are arguably crude and inconsistent. The PEI does not accurately reflect the costs of specimen collection or the way they vary. Also, coning does not apply to specialist requests, although the same scale economy applies to them. It also distorts the information available for analysis and policy-making. While the introduction of the episode cone was expected to provide an incentive to discourage high content referrals, as the pathology practices would bear the cost of the fourth and subsequent tests, an analysis of recent episode coning data has shown this not to be the case, and presumably, maintaining positive relationships with their referrers is of greater concern. Under the previous MoU arrangements, the lack of indexation allowed the government to share in these efficiencies as they accrued over time.

The second economy of scale that pathology providers have relates to the total number of specimens tested in the same laboratory. The more specimens that can be transported to a single laboratory the greater efficiencies that are possible in courier networks, and the greater capacity for investment in equipment to reduce costs. It is this scale economy that has driven the large corporate providers to consolidate and to establish large, high-volume labs. The efficiency that providers

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<sup>41</sup> <http://www.treasury.gov.au/contentitem.asp?ContentID=275&NavID=020>, accessed 7 Dec 2010

<sup>42</sup> <http://www.treasury.gov.au/contentitem.asp?ContentID=274&NavID=020> accessed 7 Dec 2010

<sup>43</sup> PricewaterhouseCoopers report *Capital Expenditure in the Pathology Sector* August 2010

derive from total volumes and market share however are not currently reflected in funding arrangements. While the MoU arrangements made connections between volume and price, which could in theory have reflected these volume economies, in practice changes made to maintain expenditure within agreed limits were not specifically directed to those areas or providers that benefited from increased volumes.

Economies of scale in pathology are so significant that there is a natural trend towards a monopoly or duopoly. The most efficient way of providing pathology services for Australia, at least for out-of-hospital services, would be to run a single, national network of laboratories. This would allow the most efficient allocation of testing to locations where the volumes can be concentrated, and would allow for the most efficient courier network. However, a monopoly provider would have little incentive to maintain high service levels for patients and doctors. It would also be likely to seek to extract higher payments from government, which would be difficult to resist, as the situation would exacerbate the information asymmetry between provider and government. A monopoly provider would also have greater ability to charge patient co-payments. However, there would also be a strong case for more direct regulation of this. A pathology duopoly carries many of the same risks, although to a lesser extent.

As a result, a key challenge for pathology policy is maintaining an adequate level of competition in the market and judging what cost should be paid for this. Given the economies of scale that large providers can achieve, it is impossible for smaller providers to compete on cost. One policy option that government could consider is paying in a way that explicitly recognises these differences, to avoid driving remaining smaller players, including the not-for-profit sector, out of the market. Another option may be to encourage the public sector to expand and consolidate in order to provide an additional source of competition. This could also encourage public providers to become more efficient across the full range of services they provide.

### **Capital Expenditure in Pathology**

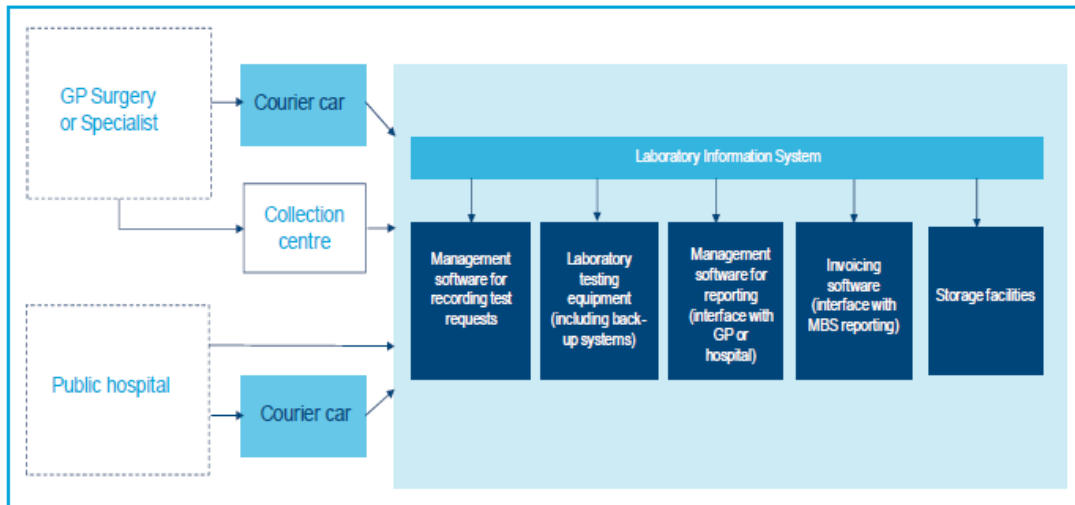
While much is known about government expenditure on pathology, information about the costs of providing pathology services, in particular the cost of capital, is not consolidated nor is it publicly available. As part of the review of pathology funding, the Review engaged PricewaterhouseCoopers to undertake a research project to understand the nature, variation and complexity of capital expenditure in pathology operations<sup>44</sup>. This report was finalised in July 2010 and was made publicly available on the department's website in September 2010.

Diagram 23 below shows the pathology test process, as identified in the PwC report.

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<sup>44</sup> PricewaterhouseCoopers, *Capital Expenditure in the Pathology Sector*, August 2010.

**Diagram 23: Pathology Test Process<sup>45</sup>**



There were several key drivers identified for investing in capital for pathology testing, volume being major driver for profitability. Substantial differences are shown in the comparison between small and larger practice capital efficiencies, as ultimately providers will invest in capital if they believe they can generate sufficient volumes to justify the additional investment. This investment can also influence market share, a primary focus of private providers.

Patient access to services is also a driver of capital investment. To ensure access to pathology for all Australians, public practices have a community service obligation to provide services in rural and remote areas. These services are however supported by private practices, which offer good rural and remote access to customers. The need to provide services in these areas however drives up capital expenditure and there are inevitable challenges in delivering services cost effectively in these areas, for example contingency provisions are essential in order to provide confidence in the service.

Cost containment is also an important driver of investment decisions. Labour costs for example take up a significant component of a pathology practices' cost structure, and therefore substituting capital for labour can often offer the most scope for cost reduction. While some areas of pathology still require a great deal of manual input and specialised interpretation, there has been a high degree of automation in the industry over the last decade, which has led to an introduction of labour-saving machinery in the pathology sector.

Finally, the most prominent type of capital expenditure investment in the pathology sector is in IT. Investment in IT is critical to both the internal operating environment of the pathology practice, as well as affecting the practice's service offering to referring specialists and GPs. IT systems are used to improve the timeliness and service attributes of test results, and it is becoming a key market differentiator for pathology practices.

### **3.10 E-Health**

The uptake of electronic health initiatives in the pathology sector is varied. Most pathology laboratories are highly automated and have the capacity to electronically send and receive pathology information. However, the manner in which they do this differs from provider to provider.

<sup>45</sup> Extract from Figure 6 of PricewaterhouseCoopers report *Capital Expenditure in the Pathology Sector*, August 2010

## **Receiving requests (e-ordering)**

Discussions with industry experts indicate that, currently, the rate of GPs undertaking e-ordering for pathology is low (lower for specialists), and mostly occurs by GPs who are commercially related to pathology companies (point to point). This is because GPs currently influence the laboratory that will provide the service to the patient, and the software used by both points is internally compatible. No external interoperability is needed. The process allows for the e-order to sit in an 'inbox' at the pathology laboratory until the patients' specimen arrives.

Independent GPs (not commercially related) mainly provide a hard-copy pathology request to their patient and the patient takes it to the pathology collection point. For these GPs, e-ordering is problematic and would depend on the compatibility of software on their desktop with the software at (possibly multiple) pathology collection centres and laboratories. There is no real incentive for medical software vendors to introduce e-ordering modules, nor is there any pressure from GPs for them to do so.

General e-ordering, when it does arrive, will involve substantial cost savings for pathology providers. Large laboratories employ numbers of staff to manually enter pathology requests into the laboratory information system, which allows automated analysis of specimens.

## **Sending results**

The majority of pathology results (more than 70%) get transmitted electronically, from pathology laboratory to GP (point to point)<sup>46</sup>.

Pathology laboratories have specifically designed their e-results in a proprietary format so that they can be accessed by the GP, but they are difficult to store into a patient's clinical record within GP medical software. Each major laboratory group has its own results delivery system and results are therefore delivered in a non-standardised format. The impact of non-standardised reporting format for pathology results may make it difficult to compare results, as each laboratory may report their findings within a different non-standardised range. For example, a patient who has had bowel cancer may need regular carcinoembryonic antigen tests to monitor any regrowth. These tests are undertaken by different laboratories using different methods, and the results provided back to the GP are dependent on the method used and the range used within that method, and therefore may not be comparable between laboratories. For the sake of continuity and comparison of results, GPs may ask patients to use one pathology provider. However, for most common pathology tests, where there is little need to compare results over time or where there are generally accepted reference ranges, this is not a concern.

It is also difficult to forward a copy of a report to another GP (unless they are within the same proprietary network) and difficult to provide to a specialists as part of a referral.

When a GP and a pathology laboratory establish a point to point relationship, the pathologist has effectively captured the GP's business. They provide results in a format that the GP becomes familiar with, which makes it difficult for them to change their arrangements of preference to another laboratory. Comparison of patient results over time is simpler (based on consistency of reporting). While the government has removed the requirement for a patient to take a pathology request generated by a GP to the specific provider indicated on the request form, GPs can still direct patients to a particular pathologist for clinically related reasons.

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<sup>46</sup> NeHTA, The Pathology Industry – Environmental Scan, 30 June 2009, pp16  
[http://www.nehta.gov.au/component/docman/cat\\_view/161-business-packages/162-epathology/256-e-pathology-foundation-documents?orderby=dmdatecounter&ascdesc=DESC](http://www.nehta.gov.au/component/docman/cat_view/161-business-packages/162-epathology/256-e-pathology-foundation-documents?orderby=dmdatecounter&ascdesc=DESC)



## Existing NPAAC requirements

NPAAC has published Requirements for Information Communication<sup>47</sup> which outline standards (required to achieve accreditation), guidelines (consensus recommendation for best practice), and comments (to provide context and clarification). One of these elements is ‘Compliance with electronic messaging standards’ which suggests:

- as a guideline - that requests and reports should comply with AS 4700.2 (and subsequent revisions); and
- as a comment – that certification of compliance of electronic messages can be undertaken by the Australian Healthcare Messaging Laboratory (AHML), which has been accredited by NATA.

At this time, compliance with electronic messaging standards is not mandatory for laboratory accreditation, and the Review’s understanding is that no laboratory has used AHML for compliance testing in the last 3 years.

## NeHTA

Discussions with the National E-Health Transition Authority (NeHTA) have identified that it is working with Standards Australia to update the current standards in order to achieve consistency.

While the next iteration of standards for pathology will facilitate interoperability and enable linkages to the personally controlled e-health record (PCEHR), there is as yet no mandated requirement for pathology providers to adopt this version of the standards.

## 3.11 Workforce

### Workforce Roles

Within the pathology laboratory there are, in general, two main roles: the medical scientist and the pathologist. The scientist performs tests on blood, other body fluids and tissues to assist clinicians in the diagnosis, treatment and prevention of disease. Scientists generally have a Bachelors degree with a major in a scientific field. The pathologist has undertaken a medical degree plus an additional 5 years specialist training in a pathology discipline and is responsible for the overall diagnosis of disease from pathology specimens, as well as providing a level of supervision to the scientists working within the laboratory. There are also laboratory assistants and other staff who do the ‘non professional’ tasks associated with pathology provision.

The ratio of pathologists and scientists vary within each field of pathology. For example in the highly automated area of haematology, the pathologist would only provide general supervision to the diagnosis of the disease, the test being run and reported by the qualified scientist. In anatomical pathology however, the role of the pathologist is essential in the diagnosis of disease, with assistance by the scientist in preparing the specimen.

Submissions in response to the first Discussion Paper identified that maintaining an adequate workforce is of concern to the sector.

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<sup>47</sup> NPAAC, *Requirements for Information Communication* (2007 Edition)  
[http://www.health.gov.au/internet/main/publishing.nsf/Content/0F6FB80B3BADE02ACA2573710010948E/\\$File/InfoCommSept07.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/0F6FB80B3BADE02ACA2573710010948E/$File/InfoCommSept07.pdf) accessed 29 September 2010.

## Supply versus Demand

The pathology sector has for some time had considerable concerns about an impending workforce shortage of pathologists. While this concern remains, expanded government support for pathology training places, including in the private sector, has improved the situation. There are also claims that there is likely to be an even greater shortage of specialist scientists qualified to work in pathology laboratories. These staff shortages may contribute to increasing workforce costs for pathology providers and could also cause reductions in quality. However, there is probably greater scope in pathology for automation to substitute for labour than there is in other areas of healthcare. Nevertheless, there may be scope for further government assistance to ensure that the sustainability of the sector is not compromised by workforce shortages.

## Impact of Technology

Technological changes are rapidly changing the pathology sector. News of upcoming technologies is circulated electronically through such means as the Dark Daily Report, and examples of recent topics include:

- Predictions suggest that the increasing rate of cancer incidence in the U.S. will drive growth in tissue-based diagnostics, through immunohistochemistry assays and the emerging market in molecular diagnostic assays<sup>48</sup>;
- Agreements between major diagnostic companies and electronics and healthcare giants in the U.S. will enable developments in the use of digital pathology, particularly for detection of cancers. Digital pathology is still an infant trend. The number of anatomic pathology laboratories that own and use digital pathology solutions remains a small number<sup>49</sup>;
- Experts predict that will change as more digital pathology vendors enter the market and competition brings down the cost to acquire and operate a digital pathology system<sup>50</sup>; and
- Increased introduction of total laboratory automation gives clinical pathology laboratories more ways to achieve significant efficiency and savings, and cope with a shortage of medical technologists. Converting to total laboratory automation can mean a 20% to 30% reduction in labour costs. With the increasing trend of retirement of baby-boomer pathologists, laboratory scientists, and medical technologists, the significant shortage of skilled clinical laboratory professionals is exacerbated. Factors such as these are likely to motivate more clinical laboratories to consider various laboratory automation solutions<sup>51</sup>.

## 3.12 Government

### Memoranda of Understanding

As a consequence of the high growth in demand in the mid-1980s and the loss of standing of pathology as a result of Public Accounts Committee Report 236<sup>52</sup> on fraud, abuse and over-servicing, there were frequent structural changes and fee adjustments within the PST, most often with the compliance and cooperation of the sector. These interactions led to the three capped MoU

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<sup>48</sup> *Dark Daily Report* - 8 September 2010

<sup>49</sup> *Dark Daily Report* - 22 July 2010

<sup>50</sup> *Dark Daily Report* - 22 July 2010

<sup>51</sup> *Dark Daily Report* - 16 July 2010

<sup>52</sup> Report 236 of the Joint Committee of Public Accounts: *Medical Fraud and Overservicing – Pathology*, 1985, Canberra

funding agreements. Under these agreements there was predictable funding for the industry and predictable outlays for the government. The risk of extraordinary demand was shared between the parties.

The last MoU became difficult to manage largely because of the debate about quantifying the impact of government policies, particularly the 2004 and 2005 measures to address the access and affordability of primary care. The strategy was successful but increased GP attendances, consequently leading to increases in demand for secondary services which had not been anticipated and were difficult to enumerate. The industry/government interface became “clogged” by debate and argument about the quantum of adjustments and distracted from the discussion of more strategic issues. In earlier periods management committees had dealt with the calculation of adjustments without being distracted from developing insights on industry and government imperatives. The earlier claims were for tens of millions of dollars whilst the latter claims were for hundreds of millions.

The final MoU was from July 2004 to June 2009. It specifically had provision for:

- funding, including patient affordability;
- PEIs;
- quality initiatives (through the Quality Use of Pathology Program (QUPP), including *HealthConnect*;
- workforce development and support; and
- policy reviews.

Since the expiry of this MoU, there has been no agreement in place with the pathology sector.

## 4 Outline of Proposals

Through consultation with the sector, nine proposals have been developed which encompass the issues raised in the submissions to the first Discussion Paper, as well as comments made by the PRCC. These proposals are:

- Tendering - tendering for pathology services;
- Tendering – aggregation of genetic testing;
- Alternative funding arrangements - volume discounting;
- Fee relativities - a review of the episode cone;
- Fee relativities - streamlining PEI items and bulk-billing incentives;
- Alternative funding arrangements - requesting assistance for GPs;
- Fee relativities - a review of Pathology Services Table items;
- Sustainability of the sector - ongoing engagement with the pathology industry; and
- Quality pathology services – enhanced reporting arrangements on safety and quality.

An additional proposal to introduce negotiated change may be a mechanism for making agreed changes to business rules under the existing pathology arrangements, and may identify a fee reduction in line with the government’s broader commitment to responsible financial management. This approach might be preferable for the sector, offer a reasonable level of certainty around the operating environment, and specify a targeting saving to be achieved over a defined period of time. This proposal would involve negotiation with the sector.

In the longer-term, these proposals could collectively feed into the development of a National Pathology Plan, which could consider broader issues such as: the ageing of the Australian population and resultant increases in cancer, obesity and chronic disease, and subsequent increases in pathology demand; and the ageing and declining pathology workforce. There are benefits from maintaining a diversified sector, which offers provider choice for patients, and provides pathologists with a range of options for practicing their profession, while ensuring high quality service provision. Proposals have been designed to achieve this, and reflect the Government’s belief that the effectiveness of current arrangements needs to be assessed, rather than assuming that current trends are appropriate and desirable.

### **Relationship of proposals**

While each of these proposals could stand alone, many of them could also be considered together as a package. However, there are some proposals that the Review does not consider should be introduced at the same time.

The Review considers that either volume discounting or tendering could be introduced, but not both. However, volume discounting could be introduced as a short-term measure, prior to a nationwide roll-out of tendering. The aggregation of funding for genetics, and associated tendering, could be undertaken concurrently with broader tendering of pathology services.

If tendering was introduced, other options, such as coning, PEIs and bulk-billing incentives, could be addressed within a tender, and therefore would not also be introduced independently.

Changes to the episode cone could be implemented with all other proposals, except for tendering.

The negotiated change proposal may draw on some of the other proposals.

Simplification of PEIs and bulk-billing incentives, the development of approaches to support GP requesting could be introduced with any of the proposals including tendering.

## 5 Tendering for Pathology Services

### Background

The Terms of Reference for the Review of Pathology Funding Arrangements require that the Review consider approaches to funding other than fee-for-service under MBS arrangements and seek to identify any specific areas of pathology that might be more appropriately supported through a different financing arrangement. One of the key tasks of the Review is to provide detailed options for implementing tendering for selected pathology services.

In addition, the Terms of Reference require the Review to consider whether current fee relativities should be changed to better reflect costs. In the absence of costing data from the sector, tendering is an approach that can help inform government about pathology costs.

### Why consider tendering?

Current funding arrangements do not give the department the capacity to collect market intelligence such as an understanding of throughput, costs, expenses and impacts for pathologists. As a result, the department is not well positioned to understand whether existing fees for individual pathology services are adequate. It has been suggested that the increased efficiencies and economies of scale associated with high volume tests and centralisation that facilitated increased efficiency through industry consolidation have not impacted evenly across the different disciplines of pathology. Some areas of pathology, such as anatomical pathology, while gaining some benefits from automation of specimen preparation, continue to be largely dependant upon individuals examining specimens and using clinical judgement to diagnose disease.

The concept of tendering is one where the government would move away from its traditional fee setting role and allow the market to determine fair and reasonable prices for services through competition. Other aspects of pathology services that are important to government, such as quality, equity and access, accountability and transparency, could be appropriately managed through contractual arrangements with providers.

### Other tendering experiences

In considering whether the use of tendering as a tool would be possible for a sector that is as complex as the pathology sector, the Review has sought to understand other, similar tendering experiences.

### *General use of tendering by the health care industry*

Tendering is used to maximise quality outcomes in procurement of goods or services. In Australasia tendering is used routinely by a myriad of healthcare suppliers for the procurement of medical technology, pharmaceuticals and medications, reagents and supplies, medical informatics and a wide range of clinical and support services, including staff. Tendering is seen as a means to encourage competition among suppliers, provide an opportunity for broad market engagement, deliver better prices, allow transparency of process and prevent fraudulent practices or favouritism to particular providers or suppliers. For these reasons all pathology providers use tendering to procure a range of equipment, reagents and sundry components that are required to help ensure their service provision is delivered at the lowest possible cost. It is not surprising that funders of pathology services seek similar benefits in terms of prices and quality assurance.

### ***State government tendering for pathology services***

State government jurisdictions within Australia have a long history of using tendering to procure pathology services for public patients but there has been great variation in the manner and scope of tendering used by each state.

Some states have used tendering sparingly and usually in order to cover particular service weaknesses or transient risks. For example, in Queensland a portion of anatomical pathology services were tendered out to private suppliers when the public sector service was unable to provide sufficient pathologist cover to meet the RCPA's reporting requirements. Once the required number of pathologists had been recruited and service standards rebuilt to a level required to gain RCPA approval, the outsourced work was returned to the public sector provider.

In contrast to this minimalist approach, Victoria has actively tendered out most of its provincial public pathology services to private suppliers for over 20 years. It is generally seen by the service funders as highly successful. Tenders have consistently led to the provision of high quality services to clinicians and patients at prices that are reported to be well below those provided by equivalent public sector services elsewhere and generally in the order of 65-75% of MBS schedule fees.

Other states report mixed results but as a general rule, tender failures or difficulties seem to have been usually related to a mix of poor tender specification, unrealistic or inflated expectation by the funder or client clinicians, overreach by the successful tenderer, unsustainable pricing or poor contract management. Each of these issues will require careful consideration in any tender process undertaken by the Australian government.

Nevertheless the Victorian experience suggests that tendering for pathology in a public sector context can provide beneficial and sustainable outcomes without leading to a monopoly supply situation or decline in quality of service. Success is dependent on a range of factors including the quality of specification as well as the skill, knowledge and expertise that is applied to the tender process and consequent contract management. It should also be noted that the state tenders cover only pathology services provided for public patients in public hospitals. Medical practitioners in both the hospital and community settings retain the freedom to request pathology services for private patients from public or private providers as they choose.

### ***Australian Government tendering for pathology services***

A number of Australian government departments have tendered for pathology services, directly or indirectly.

Over the last two decades, the Department of Veterans' Affairs (DVA) has progressively transferred the ownership of its hospitals to either public or private providers. For example, in the case of the Greenslopes Repatriation Hospital in Queensland, the hospital was transferred via a tender process to private ownership in 1995. As part of the transfer process, pathology services were also tendered out by the new owners at considerably lower cost than that previously provided by the DVA pathology service.

A more direct approach has been taken by the Department of Defence. Since 2004 the majority of pathology services required by that department to cover the needs of military personnel have been tendered out. Tendering has been deployed at a national level, with each state divided into regions. The tender process is used to discover an acceptable price which then is used as the basis of a Standing Offer Arrangement. A panel of suppliers, which may include both public and private pathology suppliers, is appointed to each region. Each Defence facility within a region chooses the provider from this panel with this choice being maintained for the life of the service contract.

Defence has been well served by this tender process and has consistently achieved prices below 80% of MBS fees, generally without PEI fees. Contracts do not use coning but may include price discounting for volume. Tendering has been deployed at a national level, contracts have been won by both public and private suppliers and the quality of service provision has met required standards. Unlike the state-managed tenders, the Department of Defence has the power to direct all referrals to the tendered panel of pathology suppliers.

### *The New Zealand experience*

In at least two major metropolitan regions of New Zealand, the regional health districts have tendered for pathology and laboratory testing services. Unlike Australia, the tenders have been for the provision of services to community patients with the contracts granting exclusive, multiyear provision of pathology services to community based physicians within that region.

Two single supplier contracts are notable: the Wellington Capital and Coast District Health Board tender of 2006 and the Auckland Regional District Health Boards tender in the same year. The Wellington contract was awarded to Aotea Pathology, a joint venture which had been formed by the merger of two previously competing private companies. The contract is for five years and has been managed with minimum disruption or controversy. In contrast, the tendering of pathology and laboratory services by the Auckland Regional District Health Boards in 2006 has been controversial, highly publicised and problematic. It is often cited as the reason why tendering should not be considered in the Australian Medicare context.

The Auckland tender was for an eight year, single supplier contract to supply pathology services to community physicians for their patients. The tender was won by Labtests but was not immediately operational due to a series of High Court challenges by the unsuccessful bidder and incumbent provider, Diagnostic Medlabs.

Labtests began operation in September 2009. In the beginning the service provision by the new provider was seen to be suboptimal. There were highly publicised reports of patient misdiagnosis, misidentification, patient injury, specimen collection problems, staff inadequacies and a range of quality issues which led to widespread, unfavourable comment by medical practitioners, the press and senior New Zealand Government Ministers.

There is no doubt that the initial transfer of service provision to Labtests was problematic. Labtests publicly apologised for the problems, admitting the company had spent too much time building its laboratory and other infrastructure at the expense of getting other key service elements in order. Since that time the situation has settled down considerably. The department has been advised that Labtests is achieving the performance standards required by the contract and there have been considerable savings in the cost of the pathology services<sup>53</sup>.

There are a number of lessons to be learned from the New Zealand experience. Tendering on the basis of single source, exclusive provision can deliver short-term financial benefit to the funder but there is significant risk of quality and service degradation if the new provider replaces a well established practice, especially if the new provider has to build and develop new laboratory and support infrastructure.

Unlike in Australia where tenders have generally been for a particular market segment or contracts let on a multi-supplier panel basis, these tenders are resulting in monopoly supply for all community patients within geographical regions and there is concern that in the long run, few providers will be

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<sup>53</sup> Consultant to the Pathology Review – Collective Wisdom

left in the market and sustained competition and the associated benefits will be lost.

In summary it may be fair to say that the Auckland experience has been the cause of concern for the Australian pathology sector. There is no doubt that the initial problems in Auckland have provided salutary lessons on the need for a comprehensive specification, a clear understanding of the risks with regard to commissioning of new services and the need for a high skill level in contract management.

### **Consultation with the Pathology Sector**

Consultation with the pathology sector on the topic of tendering has been extensive. The first Discussion Paper, which was publicly available for comment in January 2010, identified three different approaches that could be considered; ie. single supplier (monopoly); specialised supplier; and multiple supplier arrangements, and provided a brief overview of how these options might work.

Through that Discussion Paper, the issue of tendering generated a high level of responses from the sector, with 72% of submissions providing comments. Most respondents were strongly opposed to monopoly tendering and cited the New Zealand experience as one that Australia should learn from. There was also significant input explaining that the intricacies and complexities of pathology means that missing something critical within tender specifications as highly likely, and therefore this is a risky option.

Many respondents indicated their concern that tendering would lead to loss of competition and responsiveness, diminution of access, erosion of quality, and restriction of investment in research and innovation.

There was some support for tendering in rural and remote areas, to ensure adequate coverage of services. There were also a number of submissions that considered that tendering for specialised services or for low volume, expensive esoteric tests may be feasible, with genetics cited as an example. It was also suggested that this model would be useful when there is a transition of new concepts and technology from research into practice, and acknowledged that specialised supplier arrangements may be appropriate and cost effective for particular public health initiatives.

Others suggested that reducing the number of places where complex testing is performed would improve the value and quality of those assays, and that specialised complex low volume tests should be available in each state. However, there were alternative concerns that specialised tendering would compromise reporting and patient care if requests for various tests were divided to various providers.

The PRCC membership has consistently noted its opposition to tendering, and it is clear that tendering, particularly monopoly tendering, is of concern to the sector.

Discussions on the proposal of geographical tendering mirrored the concerns around tendering generally, but there were indications that existing state-based boundaries would be a better method of defining a geographical area, as anything smaller would restrict the volumes needed to maintain financial viability.

In general, PRCC members are not convinced that the suggested benefits of tendering would outweigh the disruption and were concerned that reducing costs would outweigh other priorities, and remain opposed to tendering. Concerns raised by members of PRCC include:



- a. Administrative concerns, such as: the extensive effort needed by government to develop a tender and subsequently manage contracts, and the corresponding effort needed by the sector to respond to a request for tender; the complexity of contract management; addressing specific issues and ‘intangibles’ within the specification, such as overlapping/border considerations, specific need to address times for collection, transporting etc, particularly in rural and regional areas; and capacity for the tender to be evaluated on issues other than price.
- b. Concerns about operating in a competitive environment, such as: the capacity to engage in a consortium; submission of a loss-leading bid to secure the tender and subsequent market share; competitive neutrality between public and private bidders; and allocation of market share to ensure ongoing viability.
- c. Concerns about impacting on sustainability of the sector, such as: transitional issues, where existing providers are not successful through a tender, eg. infrastructure, patient/doctor disruption; investment in technology and infrastructure; continued access and choice for patients and doctors; continued access for patient to MBS rebates; maintaining high safety and quality standards; and maintaining certainty in the sector.

## **Discussion**

The department has sought assistance from the sector to better understand the elements that comprise costs for pathology items, and has engaged consultants to work with the sector to understand the capital expenditure elements that contribute to pathology costs. It is becoming increasingly apparent that many pathology fees, historically set through Medicare arrangements, are not in line with contemporary practices. Allowing the market to set the price of high volume pathology tests through tendering deserves further detailed consideration by government.

The analysis of other pathology tendering experiences has identified abundant evidence that tendering for pathology services in Australia has been widespread, long standing, effective and has provided significant price reduction. Tendering has been used to provide services to relatively narrow segments of the patient population, in particular hospital inpatients. As a general rule, this level of tendering has not led to decreased competition or monopoly control of the market, and there is no evidence to indicate there was systematic quality degradation or increased risk to the patient.

However, this analysis has also identified a number of learning opportunities. The New Zealand experience, for example, has shown that managing transitional issues, having a clear definition of scope and understanding doctor and patient expectations, are all critical. Perhaps the more compelling argument against adoption of the New Zealand model of tendering for Australian community pathology services is based on demography and nature of government. Compared to Australia, the New Zealand population is relatively small, homogenous, geographically contained and the health delivery system does not have to deal with the complexities and conflicts which result from the dual State and Commonwealth health funding arrangements found in Australia. Further, services in Australia need to be provided to three broad populations: metropolitan; provincial; and rural and remote communities. The geographical size of this range of service coverage also brings its own problems of service logistics and clinical support, which is not an issue to the same extent in New Zealand. For these reasons it would not seem sensible to tender in Australia for single, exclusive provision of pathology and laboratory services for Medicare patients.

The pathology sector has also raised valid concerns that reaffirm that any tendering will need to be carefully developed to ensure that a myriad of concerns are understood and managed, not only through the request for tender process, but through contract management over the life of the contract and beyond. The Review would recommend that further work in this area should be

informed by a tender pilot. A pilot would have a number of benefits, such as a mechanism for identifying problems as they arise, and isolating them to a smaller subset, as well as being a smaller-scale price discovery process. This could inform the first stages of a national rollout of tendering for pathology.

It is apparent that tendering for Medicare pathology services will be a major policy change and will need to demonstrate clear benefits to a combination of patients, industry and government. Tender specifications will need to be carefully constructed so as to lead to discovery of efficient prices without risk to the quality of service provision.

The tender specification and subsequent contracts will need clear, well developed data requirements that overcome existing payment and reporting problems, but they will also need to be designed to encourage providers to work and collaborate with other providers and develop innovation in areas such as decision support systems. Success will be also very dependent on the nature of the roll-out strategy and the application of high level contract management and service transitioning skills.

Continuing analysis of approaches to tendering so far has identified other key issues that need to be considered:

- clearly designed tender specifications; recognising tender design is critical, and engaging with experts to design tender specifications may be appropriate;
- clearly defined tender deliverables and outcomes, including criteria to ensure the quality of services is maintained. The main consideration in any tender would not simply be cost, but value-for-money, which includes evaluation of the quality of the services. While potential savings need not be the primary deliverable for a tender, in determining overall value-for-money, cost is a valid consideration;
- overcoming any impact that tendering may have on inhibition of innovation to ensure that advances in technology can be accommodated and, where appropriate, encouraged;
- the appropriate length of contract to provide certainty for providers;
- a prequalifying process to ensure all potential tenderers are able to meet required service standards including the quality aspects prior to the actual tendering selection process;
- managing and minimising any inadvertent disadvantage to small providers, as small providers are generally disadvantaged in a tender if large capital expenditure required,
- the impact upon unsuccessful tenderers, as some providers may go out of business;
- the additional administrative time and cost for both parties participating in a tender process;
- and
- conducting a staged implementation that demonstrates the viability of the concept to both government and the pathology industry and allows the approach and processes to be improved over time.

### **Further Proposal - Geographic Supplier Arrangements**

While it is noted that monopoly tendering is generally opposed by the sector, an alternative proposal is now provided for further discussion. This proposal seeks to examine the feasibility of tendering for a defined geographic area, with multiple suppliers, to provide a comprehensive range of pathology tests for non-hospital patients. This proposal could:

- be based on evaluation criteria including quality and service standards as well as value-for-money;
- ensure requesting practitioners and patients have a choice of pathology providers;

- accommodate both public and private providers, subject to competitive neutrality provisions;
- be in place for an extended timeframe to enable new technology and staffing issues to be managed; and
- enable a progressive national roll-out of tendering.

Considerations in identifying possible geographic areas for the first stage of a progressive roll-out could include:

- existing level of competition;
- existing level of access and affordability for patients; and
- sufficient size to allow financially viable delivery of pathology services by multiple suppliers.

### **Preliminary analysis**

For a single provider to be able to offer a comprehensive pathology service to a region, a population of at least 200,000 people is considered necessary in order to generate enough activity. Similarly, a population of more than 400,000 people would be required to warrant two providers to service that area, and so on<sup>54</sup>. It would be possible however, for consortia of small providers, with access to specialist niche providers to whom they could refer lower volume and complex services as required, to service smaller populations and still achieve acceptable reporting times to requestors.

There are a number of geographical regions within Australia that have an adequate population within a region to facilitate tendering for pathology, such as regions of Wollongong and Newcastle in NSW, and the ACT. Where non-metropolitan centres do not have adequate population, grouping of regions could occur.

For instance, none of the rural Victorian health regions<sup>55</sup> have a big enough population to warrant two providers, with Gippsland around 240,000, Hume around 250,000, Loddon-Mallee around 293,000, the Grampians around 208,000, and Barwon South-Western around 340,000. This means that geographic tendering would need to encompass more than one rural health region, or a metropolitan region together with one or more rural regions. For example, for the purposes of tendering, Victoria could be divided into 3 areas:

1. North and West (metropolitan) together with Barwon South-Western, Grampians and Loddon Mallee (a total population of approximately 1,790,000);
2. Eastern (metropolitan) together with Hume (a total population of approximately 1,225,000); and
3. Southern (metropolitan) together with Gippsland (a total population of approximately 1,365,000).

### **Optimum number of providers**

This grouping identified above, however, would still only enable a few successful tenderers, providing comprehensive services, to maintain viability. The approach taken by the Department of Defence would seem to be more reasonable. A tender would aim to discover an acceptable schedule of services and prices which would form a Standing Offer Arrangement for a small panel of providers. In this way competition is encouraged and choice of provider is maintained. A multi provider approach also provides opportunity for the development of consortia between providers, including public and private.

<sup>54</sup> Consultants to the review – Collective Wisdom

<sup>55</sup> [www.dhs.vic.gov.au/operations/regions](http://www.dhs.vic.gov.au/operations/regions) accessed 6/9/2010

## **Range of services**

It may be appropriate to limit the tender to a number of test items and groups which are easily collected, transported and managed in a high throughput, rapid turnaround laboratory environment. Such tests might include biochemistry (P2), haematology (P1) and immunology (P3). Where there is a high dependency on pathologists for test interpretation, as well as a strong professional preference by the requestor practitioner for a particular pathologist input, these test groups might be excluded from the tender process. Anatomical pathology and cytology are such examples. A similar approach might be taken to highly specialised services such as genetics. A provider may be successful in the tender process but may also deliver a range of other services funded outside the tender arrangement.

## **Specification**

The tender specification will need to cover in detail all aspects of the service provision including (but not limited to) quality systems and audit, test and service schedule and prices, pre and post analytical arrangements, data requirements, and prices as well as service development and innovation. It will need to address expectations for services in rural and remote areas, relationships with requestors, costs to patients, and relationships with other providers, public and private, contracted and non-contracted.

In the first instance, tendering provides an opportunity to specify services that are not encumbered by the historical rules and anomalies within the current PST. As a minimum, the tender should specify the level of quality assurance required and the nature of audit and inspection. The specification will need to describe the total population, morbidity and mortality statistics and historical workloads. Similarly the tender will need to provide requesting practitioner demography covered by the contract and will need to set minimum standards for specimen collection and turnaround times as well as reporting and support communication pathways to these practices. Test and service prices should be provided without coning and the tender will need to mandate reporting of all tests to both the requesting practitioner and the government. Providers should be invited to consider volume discounting, or provide alternative approaches that would enable the government to pay a fair price in line with the cost of the service as well as alternative approaches to episode coning, to enable provision of complete data.

There is great scope for innovation within the tender specification. For example, there may be value in seeking new and innovative ways to identify and set prices for the pre and post analytical components of laboratory services. Another area of innovation may be to mandate integration of all test results from contracted providers to a single data base and reporting environment using defined data protocols, and specified approaches to meet NeHTA standards to enable integration of the Personally Controlled Electronic Health Record. This would provide great potential to limit duplicate testing and could inform the foundation work for the subsequent development of decision support systems and episodic ordering protocols.

## **Roll-out strategy**

Given that tendering carries risks around transitional arrangements and the level of skill and experience required to manage the process, a phased roll-out methodology could be considered.

## **Risks and benefits**

While many issues for tendering have already been identified, some key risks and benefits for a multi-supplier tender as proposed are provided below:

### Benefits

- It would avoid a monopoly arrangement;
- It would allow the community to have access to a wide choice of pathologists, through their treating doctors, at locations convenient to them;
- This approach would provide the department with the capacity to collect market intelligence such as an understanding of throughput, costs, expenses and impacts for pathologists. It would be a good first step towards understanding the real market;
- This approach provides transparency;
- This type of model has already been successfully elsewhere; and
- It would not be restrictive in terms of the types of services.

### Risks

- Unsuccessful tenderers would be unable to maintain commercial viability;
- There is a risk that pathology providers underbid (loss-lead) to ensure that they obtain a contract, which would have a negative impact on pricing pressures and in turn has the potential to negatively affect quality of service and access as well as flow-ons to policy if the department accepts this price discovery as true;
- The department does not currently have a firm understanding of current 'market rates';
- There would be a period of disruption for any transitional arrangements to bed-down;
- This approach would require significant administrative input to develop a tender and undertake evaluation; and
- This approach would require significant administrative support for ongoing contractual management.

## **Summary**

Tendering would be administratively complex to develop, implement and administer for both government and the sector. However, tendering has the capacity to provide business intelligence on the adequacy of existing fees. It has the potential to achieve additional outcomes, such as: to better define 'intangible' aspects of pathology service provision funded by Medicare (like availability of pathologists to advise on test selection and interpretation); to facilitate continued innovation and high productivity; to identify tests that must be bulk-billed for particular patients or in particular circumstances; and build up capacity and expertise in areas which are developing quickly, such as genetics; and bring about greater transparency.

## 6 Tendering - Aggregation of Genetic Tests

### Background

Pathology tests can be classified as specialised (complex) or routine (non-complex) based on the complexity of the testing process. In clinical pathology, specialised tests can only be performed by suitably qualified scientists. Some submissions to the Review suggested that aggregated arrangements for specialised services or for low volume, expensive esoteric tests may be feasible. There was also a suggestion that this model would be useful when there is a transition of new concepts and technology from research into practice, and acknowledgement that specialised supplier arrangements may be appropriate and cost effective for particular public health initiatives.

While there has already been substantial aggregation and centralisation of pathology services within the private sector it may now be appropriate to consider further aggregation of specialised, complex, low volume tests. In addition, there is also support for considering sensible consolidation between public and private sectors to encourage reduction of duplication.

A particular group of tests that could be suited to an aggregated model is genetics. Genetic testing raises complex issues that need to be fully explored with the patient, distinct from other forms of testing. In addition, reasonable volume of throughput is optimum, to ensure the currency of expertise by the pathologist. Aggregation of genetics is partially supported by the sector.

There are two levels (or categories) of DNA testing: Level 1, which is standard; and Level 2, which is complex<sup>56</sup>. Laboratories undertaking genetic tests are required to be familiar with the issues that distinguish the categories, to determine whether a test has the potential to lead to complex clinical issues, in which case professional genetic counselling should precede and accompany the test. These laboratories are also required to have knowledge on counselling and consent issues, as well as ethical issues that accompany genetic testing.

With genetics, the immediacy of turn-around time for tests is not (usually) a major issue as activity is predominantly non-urgent and the additional time taken to transfer samples and return tests would not impact on patient well being. It would be possible to attribute priority testing, for those that required it.

While MBS data shows that the number of genetic services is relatively small, it is acknowledged that approximately 75% of genetic services provided are not eligible for a rebate under MBS arrangements<sup>57</sup>. While restricted funding of genetics may be appropriate, the fact that these services are not available under MBS arrangements does not allow appropriate quality and safety controls to be established, as labs only require accreditation to provide MBS services. This is of concern to many stakeholders. In addition, as many services provided are not covered under MBS arrangements, data collection is incomplete. Further information from the sector regarding unfunded genetic tests would assist in further developing a policy approach, although further listings on the MBS would still be required to be assessed for safety, effectiveness and cost-effectiveness.

Grouping similar services together to increase volume encourages investment in technology, where disparate services would not. The current fee-for-service payment model does not encourage innovation within the genetics field, nor does it encourage the right level of research and development or training. An alternative funding arrangement, such as tendering, could better suit this mode of pathology.

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<sup>56</sup> NPAAC, *Classification of Human Genetic Testing*, 2007 edition

<sup>57</sup> Suthers, G, *Australian Genetic Testing Survey 2006*, Pp4

## **Proposals**

Human genetic testing may be suited to tendering because:

- current funding arrangements for genetic testing, which is largely funded by the states and territories, could be considered inequitable, with the availability and cost to patients of tests dependant on where they live;
- genetic tests for heritable gene disorders should only need to be conducted once for any individual, can require different clinical support for patients, such as genetic counselling, and may have implications for their family members; and
- there are concerns about the quality of some genetic tests, which have transitioned quickly from research to clinical use and for which there may be no current accreditation or quality assurance program available.

## **Tendering for genetics**

One possible approach to future Commonwealth funding of human genetic testing could involve a quality-focussed tender to restrict provision of selected genetic testing services to providers who meet specific accreditation requirements that essentially involve the provision of high quality services including counselling. These requirements would be in addition to the usual NATA/RCPA accreditation requirements imposed on all laboratories seeking Medicare payments.

It is proposed that this method of funding would be used for low to medium volume, highly complex testing. High volume but low complexity tests could still be funded on a fee-for-service basis through the MBS.

The tender specifications and subsequent funding would allow sufficient opportunities for research, innovation and development by the laboratories. It is envisaged that there would be multiple successful tenderers and the aim would be to have a spread of laboratories across all states. The tender would be open to public and private providers subject to competitive neutrality provisions. Funding would be applied in such a way that prevented the current situation in some states where testing is halted if maximum funding levels are reached.

Work would need to be undertaken to decide which tests would be included in the above arrangement and which tests would remain on the MBS. Experts in the genetic field and other medical specialities would be extensively consulted in this process.

Risks that would need to be considered would include:

- There is some risk of inadvertently generating inefficiencies by separating different kinds of genetic testing. The extent to which testing for genetic variations in cancers and identifying pathogens using genetics is more efficient if combined with human genetic testing is not clear. It would, however, be inappropriate to attempt to concentrate such testing services in specialist genetics laboratories, as they need to be integrated with other relevant pathology services to ensure quick and accurate diagnosis for patients.
- There may be some hesitation from states, however, state laboratories would be able to tender for the genetic testing work.

## **Approving genetic tests for public funding**

Technological advances in genetics have been rapid and this is expected to continue, with burgeoning growth in the number of tests and there is concern that the current method for assessing new genetic tests through the MSAC is considered too slow to handle the rapid growth in tests<sup>58, 59</sup>. For example, the United Kingdom's Genetic Testing Network has identified 55 genetic tests that it considers are 'of unequivocal clinical utility', but only two are currently listed on the MBS. The capacity to speed up health technology assessment of new genetic tests is a key concern for a number of pathology stakeholders. Reforms by MSAC following the Review of Health Technology Assessment in Australia are expected to assist.

There is a risk that genetics items listed on the MBS in the next few years at appropriate input-based prices will subsequently have their costs substantially reduced and there may be a tipping point in the foreseeable future where it becomes cheaper to provide a patient's full genome than to conduct analysis seeking a specific gene variation.

Given the above, the establishment of an appropriate mechanism to assist more timely consideration of listing new genetic tests on the MBS could be considered. This would continue to be based on recommendations by MSAC, but may involve establishing and supporting a dedicated sub-committee that could prioritise and evaluate genetic tests.

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<sup>58</sup> NCOPP, Submission to the first Discussion Paper, May 2010, pp8

<sup>59</sup> RCPA, Submission to the first Discussion Paper, April 2010, pp11



## **7 Alternative Funding - Volume Discounting**

The Government is keen to ensure that it is paying the right amount in the right way to ensure that patients have continued access to quality, affordable pathology services.

In any marketplace, including the pathology sector, purchasers are able leverage their purchasing power in exchange for discounts. Larger pathology companies do this to get cheaper rates for purchasing equipment and consumables in bulk. The government is seeking to apply this principle of purchasing power to obtain a discount for the provision of high-volume pathology services that benefit from economies of scale.

Large laboratories have a greater capacity to process tests at high volume, which in turn means that their economies of scale are greater, and their capacity to generate profits is greater. This proposal will move towards levelling the playing field between large and smaller laboratories.

Any discount applied in this way would at present be arbitrarily constructed because the department has found it difficult to obtain data about fee and cost relativities that would enable it to make informed decisions about how to, more equitably, share in scale economies.

The volume discounting approach is an alternative to tendering. This proposal is a simple way of extracting a share in economies of scale, in lieu of introducing a tailored approach to fee distribution and efficiency through the price discovery processes of tendering. While it is not considered that proposals of tendering and volume discounting could be introduced together, volume discounting could also be introduced to achieve a short-term outcome prior to a nation-wide roll-out of tendering for pathology services.

### **The sector**

The current Australian pathology sector comprises three large corporate providers, 103 medium-sized and smaller businesses in the private sector, and 29 public sector providers. This mix helps ensure that pathology services remain available, accessible and affordable, particularly in rural and remote areas, and to ensure healthy competition. The effect of the previous MoU was de facto to allow Government to share in the technical efficiencies of the whole sector.

Separately, there is the issue of scale efficiency, which applies variably across the sector, but which is a significant determinant of costs and margins. Large laboratories have a greater capacity to process tests at high volume, which in turn means that their economies of scale are greater. For highly automated tests, the marginal cost of each individual test decreases as the volume of tests increases, with laboratories processing the highest number of tests having the greatest economies of scale. A flat rate is paid for each test through MBS arrangements, and the department considers it appropriate to examine capturing some of this high-volume scale efficiency.

### **The proposal**

This proposal comprises four distinct elements: (1) identifying the items to which a discount will apply; (2) identifying high-volume providers of those items; (3) identifying the volume at which the scale efficiency should be realised; and (4) identifying the quantum of scale efficiency discount to be applied.

Only high-volume items that benefit from scale efficiencies should be included. In the department's view, it is chemical pathology and haematology that are the most highly automated. As it is the highly automated, high volume items that generate efficiencies of scale, it seems most

appropriate to consider haematology and chemical pathology (P1 and P2) items only.

The department considers that the point at which a discount starts to apply should be determined based on throughputs rather than expenditure. Regardless of the parameters chosen, there is inherent flexibility in this approach, with capacity to apply a scale efficiency discount in a general way, or through a more targeted approach. Robust modelling will need to be undertaken to determine the impacts of each of the variables in combination.

The quantum of the discount also needs to be determined, as well as the way it could be applied, ie. either as a flat rate or by using a scaled approach. An ascending scale of discount could apply a higher discount for greater volumes to capture the decreasing marginal cost per test with increasing volume. For example, services between 5% and 10% above the threshold could be discounted by 20% of the MBS fee, services between 10% and 20% could be discounted by 25%, services between 20% and 30% could be discounted by 30%, and so on.

### **Approaches**

A number of different approaches have been considered; at an item level; at a laboratory level; and at a corporate (APA) level. The laboratory level is considered to be most appropriate and equitable, as scale efficiencies are maximised at an individual laboratory level. The more specimens that can be transported to a single laboratory the greater efficiencies that are possible in courier networks, and the greater capacity for investment in equipment to reduce costs. Once a laboratory has sufficient throughput to cover its fixed costs, every additional test provided makes a greater contribution to profit.

It is proposed that the volume discount would only apply to high volume items, and only for those laboratories that generate sufficient volumes to warrant a discount, rather than all providers. A secondary 'eligibility threshold' can be used to identifying high-volume providers of those services; for example, those with more than 5% of the total national volume. Once the eligible laboratories reach the identified threshold, then payments would default to a discounted rate.

This model may allow for reallocation of testing between laboratories to occur within a company, designed to minimise the impact of any discounting. However, there are various individual and combined strategies that can be considered to mitigate such risks, such as establishing regulations, undertaking monitoring, as well as pitching the discount in a way that does not make it worthwhile for services to be shifted between labs.

### **Discussion**

While the examples above provide an indication of the quantum of the discount that could be applied, modelling will need to be undertaken to ensure that the impact of any discount is well understood. The more data the department receives to assist with this modelling, the better any policy will be. A small discount in the order of 5% may be considered to be a small efficiency dividend that could be generated without undue disruption to the industry, whereas a larger discount in the order of 15% would be likely to inhibit growth for efficient providers.

## 8 Fee Relativities - Review of the Episode Cone

### Background

The 'episode cone' was introduced in the mid 1990s and was the second strategy to address concerns about the exploitation of MBS through the inducement of requests for unnecessary tests. The first was in 1992 when episode initiation items were introduced to cover the some of the costs associated with the episode rather than those associated with the iterating tests. This enabled a significant reduction in test rebates and minimised the impact of high content referrals. After three years it was agreed to introduce the episode cone to make further savings, but only against high content referrals. Then, as now, high content referrals are disproportionately profitable, as successive items increasingly incur only the marginal cost of testing. The introduction of the episode cone for the first time provided an incentive to discourage high content referrals. Pathology providers had a financial incentive to communicate with their referrers and encourage logical, sequential and hierarchical investigations, as the pathology practices would bear the cost of the fourth and subsequent tests. It was accepted by the profession as a saving made against inappropriate practice with little expected impact on the incomes of most practices.

The episode cone describes an arrangement under which, in a patient episode for a set of pathology services of more than three items requested by a GP in a non-inpatient setting, the Medicare benefits payable will be equivalent to the sum of the benefits for only the three items with the highest Schedule fees. The episode cone does not apply to inpatient services, or to services requested by specialists.

### Pathology sector views on episode coning

The first Discussion Paper suggested that the current episode cone arrangement could be reconsidered, and the topic generated a substantial level of interest from the sector<sup>60</sup>.

The majority of submissions were in favour of removing the episode cone, and many noted the difficulty in getting a complete picture of pathology services in the private sector with incomplete data resulting from the unclaimed pathology activity. There were views that the cone undervalues services and pathology practices bear the costs of tests which do not attract rebates. There was also a view that coning becomes counterproductive when tests are abnormal and further testing is required. In a price controlled marketplace, providers are driven to maintain or increase market-share and are reluctant to inhibit referral or annoy referrers.

Many submissions also recognised that coning has been an effective method of capping funding, and removing the cone would have significant financial implications, possibly in the order of a 10% to 20% in expenditure. There were suggestions that increased expenditure could possibly be recouped through other methods. In one submission, prohibited practices legislation was referred to as a compelling reason for removing the cone.

Alternatively, views were provided that the episode cone should remain. The Consumers Health Forum of Australia<sup>61</sup>, for example, believes that it should remain in place as the current arrangements have allowed consumers to only be billed (usually bulk-billed) for the three most expensive tests, which has resulted in better patient access to services. In addition, the cone should also be applied to medical specialists as MBS rebates are made on the basis of the test provided by the pathologist, not on the basis of who referred for the pathology service.

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<sup>60</sup> Summary of Submissions Summary of Submissions received in response to the Review of Pathology Funding Arrangements: First Discussion Paper, May 2010, <http://www.health.gov.au/internet/main/publishing.nsf/Content/MBRT-Pathology-submissions>

<sup>61</sup> CHF, submission to the Review of Pathology Funding, 30 April 2010

The majority of stakeholders however, have suggested removing the cone, as it does not achieve its objective of managing demand for pathology, they don't get paid for all tests they are obligated to provide and recognise that the government does not get full data on testing<sup>62,63,64</sup>.

It is generally accepted that coning has been an effective way of reducing government expenditure on pathology and that the savings have been made against tests performed largely at their marginal cost. Therefore removing the cone would need to be done in conjunction with some form of cost control, particularly aimed at high content requesting, to ensure a cost-neutral impact. A risk is that high content referrals will be encouraged, even if the additional rebates are nominal.

## **Discussion**

Meetings of the PRCC acknowledged that there was very little data to support the development of options to amend the episode cone. Several PRCC members expressed their interest in providing data to support this modelling, and subsequently the department received 'unconed' data from a number of public and private sector pathologists, as well as the DVA who removed the episode cone for their veteran cohort in 2006.

Analysis of the available data has given the department good insights to the quantum of the testing provided by the pathology sector and the incompleteness of Medicare data, resulting from practices only able to claim the three most expensive tests arising from GP requests. While removal of the cone had an impact on DVA of an approximate 6% increase in expenditure, the department's analysis has shown that the removal of the cone based on the data from public and private providers for Medicare patients would equate to an increase in Medicare outlays in the order of 10-12%. The impact on individual practices would depend on their GP/Specialist mix of referrers and the frequency of high volume requests from specialists. In addition, the data provided highlighted the extent of the gaps in Medicare data. For example, two commonly requested tests, both of which are promoted for chronic disease management, HDL cholesterol (item 66536) and HbA1c (item 66551), are very frequently coned out. Medicare has no record of more than 65% of the former and more than 20% of the latter.

Based on the analysis, options for the removal of the episode cone, to allow payment for all tests undertaken with a sliding scale of rebates for multiple tests and that apply equally to GPs and specialists, have been discussed with the pathology sector through the PRCC<sup>65</sup>. However, indications were that a nominal payment for tests provided outside of existing coning rules would be acceptable as a simpler mechanism to collect robust data for analysis, and that any moves for parity between GPs and specialists should be progressively introduced over time.

## **The proposal**

This proposal seeks to remove coning to allow payment for all tests undertaken, with a nominal payment for tests performed in addition to the first three within an episode for GPs. It is also envisaged that this will apply to pathology requests from specialists for the first time, with a nominal payment for tests performed in addition to the first five within an episode for specialists.

This proposal will therefore give providers some payment for all tests performed and provide comprehensive data to Medicare Australia on all tests performed.

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<sup>62</sup> IVD Australia, submission to the Review of Pathology Funding, 29 April 2010

<sup>63</sup> RCPA, submission to the Review of Pathology Funding, 30 April 2010

<sup>64</sup> AMA, submission to the Review of Pathology Funding, 6 May 2010

<sup>65</sup> PRCC meeting of 9 November 2010.

A small nominal payment could be made for all services in addition to the first three that are currently covered by the cone, for GPs. For example, for the first three tests, an 85% rebate could be paid, then a nominal 20 cents per test for each service could be paid. Similarly, a reduced rate could also be introduced for specialists. However, as coning does not currently apply to specialists, this could be introduced after a higher number of tests requested. For example, for the first five tests, an 85% rebate could be paid, then a nominal 20 cents per test thereafter. Preliminary analysis shows that approximately 6% of out-of-hospital requests from specialists include more than five tests.

While the nominal amounts outlined in this proposal are indicative only, this proposal is based on the assumption that the increase in funding for services provided through GP referrals will be offset by the decrease in funding for services provided through specialist referrals. Further modelling would need to occur to establish the appropriate rates. This proposal includes scope for flexibility, including a staged approach to implementation. During the transition phase, separate models could apply to GPs and specialists, but these would be progressively aligned over time.

### **Benefits and Risks**

This model is likely to benefit pathology providers who would be paid for conducting all tests from GP requests, up from three. However, whilst such payments may be at or below the marginal cost of testing, they may also provide a perverse reward for those practices that disproportionately benefit from high content GP referrals.

It is possible that specialists would not view this proposal favourably, as items beyond five would attract reduced rebates for their patients, where this has not previously been the case.

The risk of growth in referral content and subsequently in outlays would need to be carefully managed by the department. The proposed rebates will require actuarial estimation prior to their introduction and close monitoring and possible adjustment thereafter if required.

## 9 Fee Relativities - Streamlining Patient Episode Initiation Fees and Bulk-Billing Incentives

Patient Episode Initiation (PEIs) fees are captured in Group P10 of the PST and are intended to help defray the cost of collecting and managing specimens for pathology testing. A Specimen Referred item is also available in Group P11 of the PST for the transfer of specimens between laboratories.

PEIs were introduced for private sector pathologists in 1992 as a means of separating test costs from the non-iterative elements of delivering pathology services, such as specimen collection, storage, transportation, reporting and the raising of accounts. Since then there have been several amendments to the PEIs including the introduction of nominal PEIs for public laboratories in 2007. Under the former MoU with the pathology sector, there was an intention to move towards parity between the public and private sectors.

Current PEI arrangements have evolved through decisions taken over time, based on the issues of the day. The department is now considering further changes which, although arbitrary, are reflective of current government imperatives.

### Issues

The PEI fees are an ongoing issue within the pathology profession. PRCC members have noted that the PEI fees are cumbersome, duplicative and have not kept pace with structural and market changes. Issues concerning the relativities between collection circumstances was raised in response to the first Discussion Paper. The suitability of fees in rural and remote areas has also been identified in recent documentation from the sector<sup>66</sup>.

In addition, an issue of contention is the differentiation between private and public providers. It is now common practice for public laboratories to accept private work and to operate as independent business units that pay a hospital, state or territory for the infrastructure they use. Because of this, some in the pathology sector argue that public and private providers compete equally for pathology work and that MBS payments should not differentiate between private patients in public hospitals and private patients in other settings. Some stakeholders however believe that extending the PEI to include public pathology is in conflict with the original reasons for creating the PEI payments, that is to cover the expenses unique to private pathology practice. It is acknowledged that the former MoU with the pathology sector intended to move towards parity between the public and private sectors.

Any alteration to PST group P10 would affect group P13, the bulk-billed pathology episode incentive items. These items are bulk-billing incentive payments, ranging from \$1.60 to \$4.00, and are directly linked to the PEI group.

During discussions with the PRCC<sup>67</sup> it was acknowledged that while the exact cost coverage of the existing PEIs is unclear, pathology providers do incur non-iterative, episodic costs. What proportion of the costs of providing an episode of pathology are episodic and what proportion relate to the specific tests requested is difficult to establish and likely to vary between providers. It can also be affected by other considerations, such as the nature of the request, the location, and acute needs of the patient.

The current PEIs provide different rebates (and bulk-billing incentives) intended to reflect different

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<sup>66</sup> AAPP, *Pathology Issues*, pamphlet, circa October 2010.

<sup>67</sup> Pathology Review Consultation Committee meeting of 16 June 2010

costs incurred by APAs according to different circumstances of episode initiation. Below, the department has provided a proposed approach to address some issues of concern to the sector, as well as issues of importance to government.

### **Proposed approach**

This proposal aims to simplify current PEIs by rolling up similar services from 19 items into four items. The bulk-billing incentive items associated with PEIs will also be modified and simplified under this proposal to a single bulk-billing incentive item. Unlike the current system, this proposal will pay private and public providers the same fee, subject to competitive neutrality provisions.

The proposal also aims to introduce a new PEI item for collections in rural and remote areas, reflecting the additional costs borne by providers in collecting in these situations, as well as enabling collections in special circumstances (yet to be defined, but could include such specimen collections as those for PAP smears) to be paid a higher rate.

The four items proposed are PEIs for:

1. Rural and remote collections, identified through: ACCs that exist within identified rural and remote areas; or through patient/GP address, for those rural and remote specimens that are not collected at an ACC;
2. Inpatient collections and special circumstances collections;
3. Collections at residential aged care facility and other institutions; and
4. All other collections, including collection centres, home visits, those collected in doctors' surgeries and those involving self collection of specimens.

The PEI fees could be determined based on the redistribution of funding attributed to the existing items that have been rolled into the new collective item or could be calculated based on evidence about how episodic costs vary for these types of collections. It is anticipated that the fee would be weighted in descending value, with the fee for rural and remote collections being the highest. These new items and associated fees could be applied to both public and private laboratories.

### **Views of the Sector**

An earlier version of this proposal, which included removing the current PEIs for inpatient services, GP collections and self collections, was discussed with the PRCC<sup>68</sup>. Their view was that the pathology sector prefers that the PEIs for in-hospital collections, GP collections and self collections to remain. On this basis, they have not been excluded from this proposal. It is also proposed that the associated funding would be redistributed to other PEI items so that the funding remains within the sector. To ensure equitable competition, public providers will only be able to claim 'parity items' if competitive neutrality provisions are met. Recommendations on competitive neutrality provisions are available and these would need to be adopted to meet the special circumstances of pathology. State and territory governments would need to be involved in this process from the early stages.

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<sup>68</sup> Pathology Review Consultation meeting of 9 November 2010

**Benefits/Risks**

Patients are likely to benefit from the proposal if the incentives for providers to bulk-bill are increased under this proposal.

The public sector would benefit from parity of PEIs fees, but if public providers do not meet competitive neutrality provisions, an additional PEI for public laboratories at the current rate of \$2.40 could be maintained.



## 10 Alternative Funding Arrangements - Requesting Assistance for GPs

Given that over the last decade GP pathology requesting has steadily increased and around 70 percent of all health care decisions involve a pathology investigation, it essential that the right tests are requested. Despite being subject to many different pressures including: undifferentiated patient groups; increasing chronic diseases and co-morbidities; lack of time to keep up with new evidence and new tests; GPs have been doing an excellent job when ordering pathology. The proposals suggested below are designed to continue and enhance appropriate requesting.

### Background

GPs appear to be undertaking a wide range of requesting. Evidence of this is seen through an analysis undertaken of GP pathology services that were requested on the same day that a 45 year old health assessment (item 717) was undertaken. The data shows that 44% of 45 year old health assessments have accompanying pathology, with approximately 20% of pathology services comprising just five different combinations of pathology tests. The remaining health assessments have pathology comprising a combination of one or more of a small number of pathology tests including: multiple simple chemistry tests; HDL cholesterol; glucose tolerance; iron studies; B12 and/or folate; vitamin D; PSA; TSH quantification; thyroid function; urine examination; tissue biopsy; and cervical smear.

A study of the impact of the use of general practice computer systems on the ordering of pathology<sup>69</sup> identified a number of factors that influence GPs in their ordering of pathology. Of all the factors, the ones identified by the participants as likely to have caused an increase in requests per episode are medico-legal reasons and consumer expectations. GPs are clearly concerned about their medico-legal duty of care and the prospect of missing a diagnosis which might be detected by a pathology test.

### Proposals

#### 1. Episodic Panels

There is growing international interest in using episode payments as way of improving healthcare quality and controlling costs. An episode payment system reduces the incentive to overuse unnecessary services within the episode, and gives healthcare providers the flexibility to decide what services should be delivered, rather than being constrained by fee items and amounts.

The concept of 'episodic payments' (or payments for episodic panels) is a single price for all of the services needed by a patient for an entire episode of care (e.g., all of the inpatient and outpatient care they need after having a heart attack). While this is the broadest possible definition, pathology service(s) can also be defined as episodes, and can therefore also be considered for development of episodic panels.

Preliminary analysis of data by the department has provided insights into common combinations of items. Some of these associations are clinically understandable whilst others would require more insights into the circumstances of their initiation to interpret appropriately.

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<sup>69</sup> *A study of the impact of the use of general practice computer systems on the ordering of pathology* – Michael Legg & Associates, IRIS Research, the University of Wollongong and Dr Ian Cheong – May 2004

Increasing the department's understanding of the aggregation of multiple items when their association is clinically relevant will be particularly pertinent if the government proceeds to on-line requesting with decision support software. It is envisaged that, when clinical circumstances warrant it, clinicians will be prompted to order all those tests which are recognised as relevant, through decision support tools (as discussed below).

The department will work with the pathology and requesting sectors to examine possible groupings of tests for inclusion in episodic panels that are clinically appropriate. A mechanism will be established to allow for all interested stakeholders to be included in this development work.

Episodic panels could also be of benefit to specialists.

## **2. Electronic Decision Support Tools**

Another proposal is to establish a process within the department, inclusive of bodies such as NeHTA, RCPA, RACGP, NPAAC and the AMA, to look at how to best utilise the outcomes from various decision support projects including those already completed and those currently underway. The aim is to facilitate integration of all related work into a computer-based package aimed at enhancing pathology requesting by GPs.

A key issue will be the development of an approach that makes obtaining and using decision support tools desirable for GPs. It is critical therefore that the clinical content:

- is appropriate and relevant to GPs;
- is easily and instantly accessible;
- reflects the most current guidelines; and
- has architecture established for ongoing review.

Once the clinical content is agreed, a set of generic technical specifications could be developed in a way that would encourage the medical software industry to further refine the product and take it to market in a competitive way. This would require discussion with industry representative groups to ensure the specifications are appropriate. NeHTA would play a major role in this aspect of the work as it needs to be integrated into other development work in the electronic pathology space.

Work on the above two proposals will need to be integrated with the work being undertaken by the NPS on GP requesting of pathology.

## **3. E-Health and Pathology**

The uptake of electronic health initiatives in the pathology sector is varied. Most pathology laboratories are highly automated and have the capacity to electronically send and receive pathology information. However, the manner in which they do this differs from provider to provider.

General e-ordering, when it does arrive, will involve substantial cost savings for pathology providers. Large laboratories employ large numbers of staff to manually enter pathology requests into the laboratory information system, which allows automated analysis of specimens.

The majority of pathology results (more than 80%) get transmitted electronically, from pathology laboratory to the GP. Pathology laboratories have designed their e-results in a proprietary format so that they can be accessed by the GP, but are not always compatible with a patient's clinical record

when different medical software is used. Each major pathology provider has its own results delivery system and results are therefore delivered in a non-standardised format.

Also of concern is the capacity for public sector pathology providers to respond to any standardised e-transactions because of the extent to which their pathology information systems are so integrally linked to broader health care information systems used in hospitals and area health networks.

Standardised formatting is a key issue to be overcome and the department has been working with NeHTA on this.

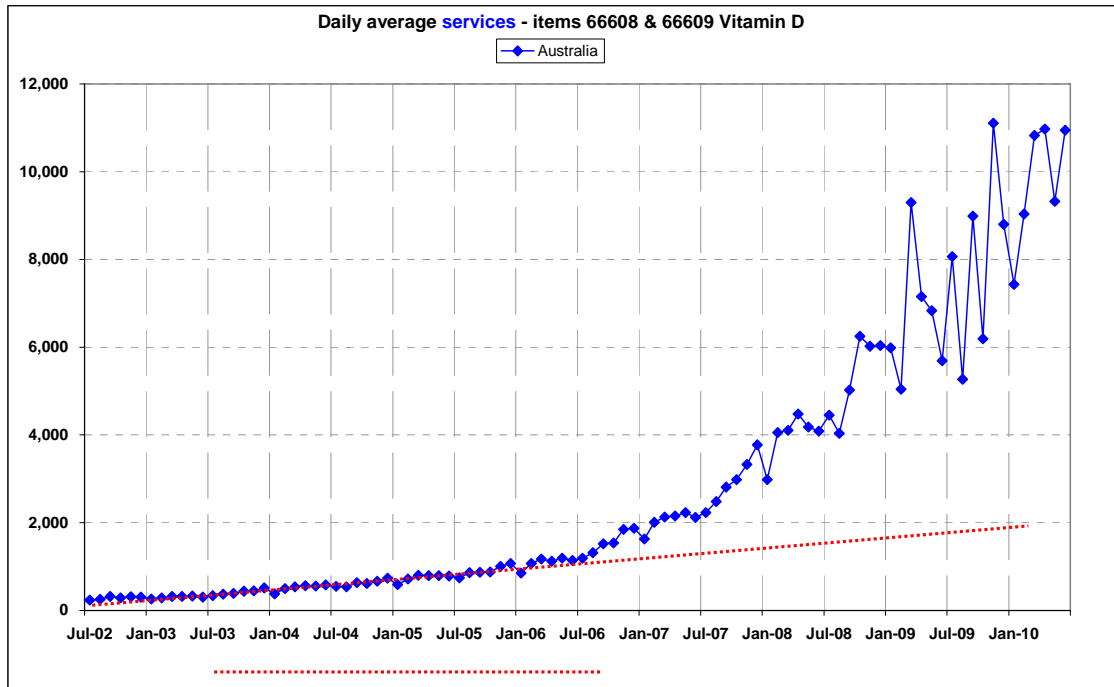
While the next iteration of standards for pathology will facilitate interoperability and enable linkages to the personally controlled e-health record, there is no mandated requirement for pathology providers to adopt this version of the standards at this stage so consideration of adopting incentives or mandating adoption is needed.

# 11 Fee Relativities – Vitamin D Testing and a Review of Pathology Services Table Items

## Vitamin D Testing

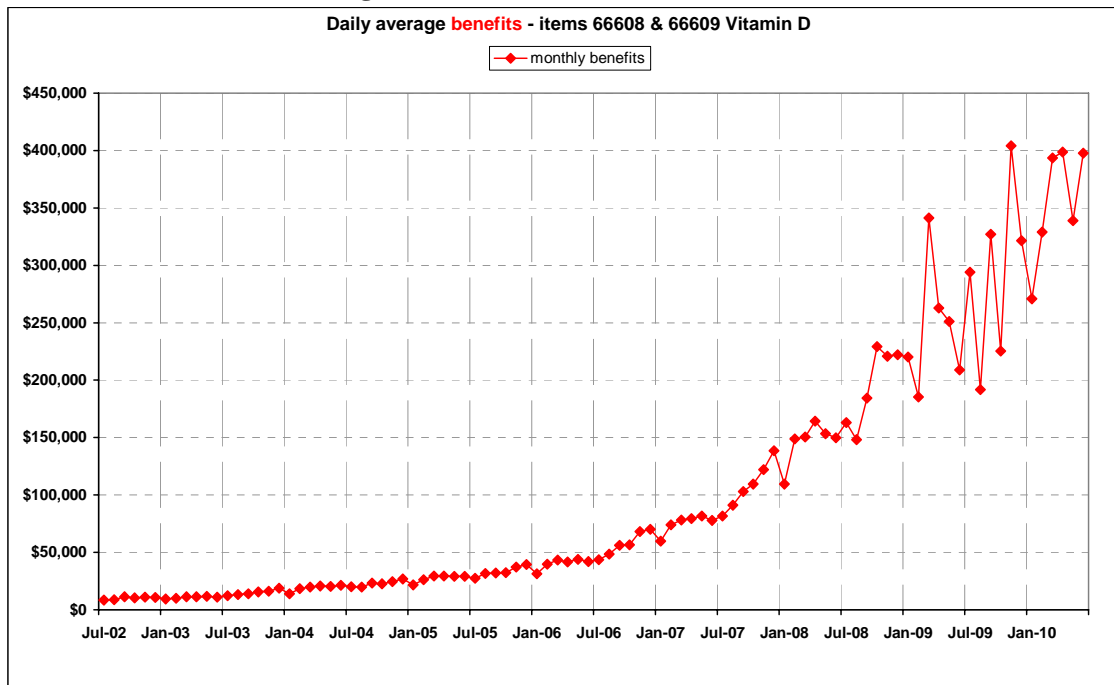
The department has monitored the large increase in the volumes associated with vitamin D testing. The current MBS item 66608 allows for testing of the quantitation of vitamin D in blood, urine or other body fluid without restriction. There has been a massive increase in requests for item 66608. The number of tests for this item has increased from 22,670 in 1999/2000 to 2,219,553 in 2009/10, with associated expenditure increased from just \$0.8 million in 1999/2000 to \$80.8 million in 2009/10.

Chart 24: Vitamin D –Average Services <sup>70</sup>



<sup>70</sup> MBS data

Chart 25: Vitamin D –Average Benefits <sup>71</sup>



It has been acknowledged by some PRCC members that changes in technology have reduced the costs associated with the test, and that the fee may be too high. As such, PRCC asked the PSTC to review the test and the associated item descriptors. The NPS has also decided independently that it will review the usefulness of the test.

Understanding the drivers of growth in vitamin D testing is difficult. Scientific literature shows increasing evidence for the clinical implications of low vitamin D and that this has been reflected in broader media reporting. However, as some pathology stakeholders have conceded that the current test appears relatively over-remunerated, there is concern that another driver of demand may be marketing by pathology providers.

There are some concerns about the accuracy of new methods developed for measuring vitamin D levels. The NPS<sup>72</sup> has identified that in Australia vitamin D is measured by a number of different assays. There is however, considerable variability among the various assays available, as well as among the different laboratories that conduct the analysis. The precision of two common commercial vitamin D assays used in Australia was investigated in 2006-07, which involved eight clinical laboratories in Australia and Canada<sup>73</sup>. A high level of variation was found between the laboratories, with only one measuring vitamin D with excellent precision. As a result of this study, the authors suggested that until this level of variance can be reduced, results should routinely include a statement of measurement uncertainty. The currently accepted best method for measuring vitamin D is mass spectroscopy. However, this involves a very costly machine. Newer methods for measuring vitamin D are cheaper to provide, but also appear to be less accurate.

A further complicating factor in the Review's consideration of vitamin D is the cost-effectiveness of testing at all. Vitamin D levels can be increased through simple lifestyle changes to increase sun exposure, although this needs to be balanced with protecting against sun exposure that can cause skin damage. Supplementation of vitamin D through medication is relatively low cost and safe,

<sup>71</sup> MBS data

<sup>72</sup> NPS, *Vitamin D testing; formative research preliminary report*, 10 August 2010

<sup>73</sup> NPS, *Vitamin D testing; formative research preliminary report*, 10 August 2010

with little danger of toxicity. Some clinical guidelines have recommended vitamin D supplementation for at risk groups without the need for pathology testing.

The Review has had difficulty establishing an appropriate evidence base regarding the costs of provision of vitamin D testing. Several providers have submitted information to the department relating to the direct test costs for performing vitamin D assays. While not directly addressing the indirect (overhead) costs associated with the performance of the test, this information indicates that the current MBS fee is significantly greater than the costs of service provision, even if overhead costs are significant. It is also becoming clear through information submitted that other tests are similarly over-remunerated and may present an opportunity for government to better reflect the costs of service provision through reducing the fee.

### **The MBS Quality Framework**

All pathology items will become subject to new processes being developed for the MBS as a whole. The MBS Quality Framework is a measure originating from the 2009/10 Budget and its purpose is to enhance the evidence-base of listed items, improve the financial sustainability of the MBS and ensure the MBS supports safe, effective and quality health services. It has two relevant elements:

#### *Reviews of Existing Items*

A key component of the Quality Framework is the development of a systematic approach to reviewing existing MBS items to ensure they reflect contemporary evidence, offer improved health outcomes for patients and represent value-for-money.

The MBS review process will involve several stages from identification to decision implementation, being:

- Environmental scanning – identifying potential review topics;
- Prioritisation and scoping of potential reviews;
- Evidence-based review of selected services;
- Advice to Minister;
- Government decision; and
- Implementation.

Each review will be evidence-based and fit-for-purpose. Larger reviews will be conducted by a relevant independent consultant with experience in health service evaluation and health technology assessment. Full details about this process can be found at the following link:

[http://www.health.gov.au/internet/main/publishing.nsf/Content/Review\\_MBS\\_Items](http://www.health.gov.au/internet/main/publishing.nsf/Content/Review_MBS_Items)

#### *Fee Setting*

The Quality Framework will include a new approach to MBS fee setting for new and existing items. Currently, most MBS fees are set through comparison and negotiation. This approach risks inequity, perverse incentives and inappropriate comparison.

It is recognised that there are unique issues with fee setting in pathology which relate to issues of service volume and the decline in marginal cost per test with increasing volume, and stakeholders will have a chance to comment on a draft methodology in the coming months.

## **12 Sustainability of the Sector - Ongoing Engagement with the Pathology Industry**

The government has previously engaged with the pathology sector through a series of MoUs. The last MoU expired on 30 June 2009 and the government decided not to continue with this model of agreement.

Consultations with the sector have identified however, that this type of arrangement provided assurance to the industry, allowing security for investment, employment and innovation. To continue to provide this stability it is proposed to engage regularly with the sector.

### **Proposal**

Quarterly meetings with pathology stakeholder organisations could be held with the main pathology representative groups invited. Representation from consumers and small and medium-sized pathology providers would be encouraged.

Two different types of meetings could be held - one for professional bodies such as the RCPA, AMA, RACGP, Australasian Association of Clinical Biochemists and Australian Institute of Medical Scientists to focus on clinical issues, and one group focussing on the business side of pathology to include groups such as the AAPP and the NCOPP along with business development managers, Chief Financial Officers and Chief Executive Officers of individual companies.

These meetings would allow stakeholders to discuss any concerns they may have but neither group would be a decision-making body. Advice received through these meetings would help inform the department as part of providing policy advice to government. It should be noted that while the department is prepared to consider issues identified by industry and provide advice to the government on these matters, it is unable to provide guarantees on issues discussed as it is the government that makes all final decisions about pathology and associated funding.

These meetings would complement advice received through other formal advisory mechanisms and it may be useful to invite representatives from ongoing expert pathology committees such as the PSTC and the NPAAC to participate in these meetings to ensure there is a shared awareness of current stakeholder views.

In addition to the ongoing mechanisms outlined above, the department may also, if the need arises, establish short-term committees to discuss specific issues. The establishment of the PRCC is a good example of how this would work.

## 13 Quality Pathology Services – Enhanced Reporting Arrangements on Safety and Quality

To ensure that quality and safety issues remain at the forefront of pathology priorities for the government and the department, there is a need to establish regular reporting from relevant experts to government on relevant trends. The NPAAC plays a key role in ensuring the quality and safety of pathology services. NPAAC's role could be strengthened to enable it to highlight areas of concern and provide assurance that the Australian accreditation framework proactively addresses priority issues.

NPAAC's current roles and responsibilities are outlined in the *Constitution of the National Pathology Accreditation Advisory Council Order* (Order-in-Council) which is linked to the *National Health Act 1953*. NPAAC's role allows it to provide advice to commonwealth, state and territory governments on a range of accreditation-related issues, including:

- development of policy for accreditation of pathology laboratories;
- introduction and maintenance of uniform standards of practice in pathology laboratories throughout Australia;
- adoption of coordinated legislation and administrative action in providing pathology services;
- initiation, promotion and coordination of educational programs about pathology laboratory practice; and
- provision of advice about accreditation of a particular pathology laboratory at the request of a Commonwealth, or State or Territory Minister.

There is provision in the Order-in-Council for NPAAC to report in writing to the Minister after each meeting with recommendations about matters dealt with at the meeting. However, there are currently no specific requirements to report to government more broadly on quality and safety matters.

### Proposal

It is proposed that NPAAC develops a three year strategic plan by the end of 2011, and from 2012, provides an annual report to government which:

- summarises its work over the previous 12 months;
- details current accreditation-related issues and how they are being dealt with;
- identifies potential issues of concern and provides solutions to address these issues via refinement of the accreditation framework.

Exact details of the reporting requirements would be determined by NPAAC itself, in consultation with the department and relevant state and territory health authorities. NPAAC does not currently receive summary information from the pathology accreditation assessment agencies on identified issues and trends so consideration will need to be given to what data could be made available to support NPAAC in this proposed reporting activity.

An amendment to the NPAAC Order-in-Council and/or assessment agency agreements with Medicare Australia may be required if these proposals proceed.



## 14 Negotiated Change to Existing Arrangements

Through its research, the Pathology Review has identified a number of areas of pathology that could be changed to deliver efficiencies, and assist with sustaining the pathology sector over time. However, it may not be appropriate to make any (or many) changes to the existing system.

It is acknowledged that the Australian model, while not without flaws, has many strengths. It has a relatively stable environment, which provides access for the majority of people to excellent quality pathology services. Existing arrangements are currently responsive to service demands of doctors and patients, and compete on level of service, not price. Sophisticated logistics allow high levels of access across Australia.

There are a number of changes that have been made over recent times to pathology arrangements, such as removing ACC restrictions, removing 6<sup>th</sup> ladder items, and removing PEIs for co-located ACC and APLs, the effects of which had not yet had time to fully flow through the system. Similarly, a recent change to legislation, which is seeking to provide the patient with the choice of pathology provider, has been amended through Parliamentary process. The impact of this change also needs to be understood. In addition, there is a recent depression in the volume of pathology, the cause of which is unclear, and there is uncertainty about any long-term effects.

### Discussion

A proposal to introduce negotiated change may be a mechanism for making agreed changes to business rules under the existing pathology arrangements, and may identify a fee reduction in line with the government's broader commitment to responsible financial management. This approach might be preferable for the sector, offer a reasonable level of certainty around the operating environment, and specify a targeting saving to be achieved over a defined period of time.

This proposal would involve negotiation with the sector to achieve a mutually agreed outcome. Should the sector be interested in this approach, it should consider:

- Delivering savings, including alternatives that ensure a fair distribution of impact across small and large providers, for example, a negotiated form of volume discounting;
- Enabling the ongoing provision of data equal to what would otherwise been achieved through implementing policy change;
- A mechanism for ongoing engagement between government and the sector to achieve greater transparency of the costs of providing tests;
- Alternative approaches to achieving some changes to arrangements that are important or necessary, such as: financing genetics; supporting GPs when requesting pathology; reviewing PST items; ongoing forums for engagement with the industry; and reporting on safety and quality issues.

## 15 Summary

The department has engaged extensively with stakeholders throughout the Review and has developed a series of possible proposals, that could be considered either independently, or in combination. These possible combinations are discussed in more detail below.

### **Tendering**

Should government decide that tendering is the preferred approach, then the Department considers that tendering should not be introduced in addition to the proposal to introduce volume discounting. These two proposals are mutually exclusive. However, elements of some of the other proposals could be included within a tender process. The episode cone and PEI proposals, for example, may not be necessary depending on the inclusions in a tender.

Any changes to genetics would be independent of a broader tendering arrangement, but possibly part of its own tender process.

If tendering is rolled-out, then other proposals, including volume discounting, could be implemented in all areas except those covered by the tender until such time as the roll-out is complete.

A package for tendering could include:

- Tendering;
- Genetics;
- Episode cone (based on existing fee-for-service arrangements); and
- Streamlining PEIs and bulk-billing incentives (based on existing fee-for-service arrangements).

Other proposals of: supporting GPs when requesting pathology; reviewing PST items; developing engagement strategies with the sector; and reporting on safety and quality issues; could also progress in addition to the tendering package.

### **Volume discounting**

As indicated above, the proposals for volume discounting and tendering are mutually exclusive, and should not be implemented together.

Other proposals, such as streamlining PEIs, reviewing the episode cone, aggregation of genetics, would all be able to be implemented in conjunction with volume discounting.

A package for volume discounting could include:

- Volume discounting;
- Genetics;
- Episode cone; and
- Streamlining PEIs and bulk-billing incentives.

Other proposals of: supporting GPs when requesting pathology; reviewing PST items; developing communication strategies with the sector; and reporting on safety and quality issues; could also progress in addition to the volume discounting package.

### **Episode cone**

The episode cone proposal could be implemented with any of the other proposals. However, if tendering were introduced, the episode cone could be addressed more broadly within a tender, and therefore may not also be introduced independently.

### **Genetics**

Genetics is a stand-alone proposal that could be implemented with any of the other proposals.

### **Streamlining PEIs and bulk-billing incentives**

The proposal to streamline PEIs and bulk-billing incentives could be implemented with any of the other proposals. However, if tendering were introduced, the PEIs could be addressed more broadly within a tender, and therefore may not also be introduced independently.

### **Other proposals**

Other proposals of: supporting GPs when requesting pathology; reviewing PST items; developing communication strategies with the sector; and reporting on safety and quality issues; could progress in addition to any of the other proposals.

## 16 Commonly Used Acronyms

AACB	Australasian Association of Clinical Biochemists
AAPP	Australian Association of Pathology Practices
ACC	Approved Collection Centre
AIMS	Australian Institute of Medical Scientists
AMA	Australian Medical Association
APA	Approved Pathology Authority
APL	Approved Pathology Laboratory
DVA	Department of Veterans' Affairs
MBRTG	Medical Benefits Reviews Task Group
MBS	Medicare Benefits Schedule
MoU	Memorandum of Understanding
MSAC	Medical Services Advisory Committee
NATA	National Association of Testing Authorities
NeHTA	National E-Health Transition Authority
NCOPP	National Coalition of Public Pathology
NPAAC	National Pathology Accreditation Advisory Council
PEI	Patient Episode Initiation
PRCC	Pathology Review Consultation Committee
PST	Pathology Services Table
PSTC	Pathology Services Table Committee
RACGP	Royal Australian College of General Practitioners
RCPA	Royal College of Pathologists of Australasia

Any queries in relation to the contents of this Discussion Paper can be directed to the Medical Benefits Reviews Task Group at [mbrtg@health.gov.au](mailto:mbrtg@health.gov.au).