

Review of the  
Pathology Services  
Accreditation Act 1984

Discussion Paper



# **Review of the Victorian Pathology Services Accreditation Act 1984: Discussion Paper**

**Submissions to the Review Panel must be  
received by close of business, Friday 10th August**

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The views expressed in this paper are those of the Review Panel. This paper has been prepared solely to facilitate discussion and does not represent the policy of the Victorian Government.

16 May 2001

The Honourable John Thwaites MP  
Minister for Health  
Parliament House  
MELBOURNE 3000

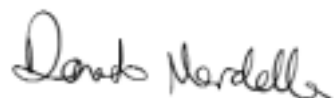
Dear Minister

In October 2000, you invited me to Chair a panel of experts charged with the task of reviewing the *Pathology Services Accreditation Act 1984* and associated regulations. I accepted your invitation with much enthusiasm and am now pleased to submit the Panel's Discussion Paper for your consideration and release for public comment.

The pathology services accreditation legislation governs the conduct of pathology testing in Victoria through a state-based accreditation system and establishes the Pathology Services Accreditation Board to administer the legislation on your behalf. Although the impetus for the review of the legislation was provided by the need to meet Victoria's obligations under the National Competition Policy Agreements, the Panel accepted the challenge to consider the legislation in the context of today's health system, and in light of increased consumer awareness about health issues and demand for the delivery of quality and safe health services. The Panel has been mindful that since the Pathology Services Act was assented to in 1984, the Victorian health system has been subjected to enormous change and while some amendments have been made to the Act since that time, it is in need of review and 'modernisation'.

In this Discussion Paper, the Panel has sought to describe the characteristics of the pathology services industry and the way in which the industry is governed not only in Victoria but Australia-wide. In so doing, the Panel has identified a number of issues and has posed a series of questions in its endeavour to 'tease-out' these issues with consumer and industry input. Consequently, comments and views are now sought from individuals and organisations with an interest in how pathology services are regulated. The Panel will consider these and then prepare a final report for Government.

Yours sincerely



DON NARDELLA MLA  
CHAIR  
PATHOLOGY SERVICES ACCREDITATION LEGISLATION REVIEW



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# Abbreviations and Acronyms

APA	Approved Pathology Authority
APL	Accredited Pathology Laboratory
APP	Approved Pathology Provider
ARMC	Austin & Repatriation Medical Centre
CoAG	Council of Australian Governments
HIC	Health Insurance Commission
HSC	Health Services Commissioner
ISO	International Standards Organisation
NATA	National Association of Testing Authorities, Australia
NCP	National Competition Policy
NCSP	National Cytology Screening Programme
NPAAC	National Pathology Accreditation Advisory Council
OECD	Organisation for Economic Cooperation and Development
OH&S	Occupational Health and Safety
PSAB	Pathology Services Accreditation Board
RACGP	Royal Australian College of General Practitioners
RCPA	Royal College of Pathologists of Australasia
RIS	Regulatory Impact Statement
VCAT	Victorian Civil and Administrative Tribunal

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# 1. Introduction

An independent Review Panel established by the Minister for Health, is conducting a review of the *Pathology Services Accreditation Act 1984* (the Act) and associated regulations. The Review Panel comprises:

Mr Don Nardella, MLA	Member for Melton (Chair)
Dr Chee-Wah Cheah	Consultant, Law & Economics Consulting Group
Professor Stephen Cordner	Director, Victorian Institute Of Forensic Pathology
Ms Kay Currie	Consumer representative, Health Issues Centre
Dr Graham Rouch	Consultant

Dr Gordon Whyte is assisting the Review Panel as technical advisor.

This review is being undertaken in response to the Victorian Government's commitment to National Competition Policy (NCP) and is part of an extensive program of legislative reviews across all Victorian Government portfolios. While NCP obligations have led to the commissioning of this review, the matters to be considered will not be strictly limited to the issue of restrictions on competition. Instead, the opportunity will be taken to review the legislation as a whole. This approach reflects the fact that boundaries between competition and other regulatory issues are often indistinct, together with the fact that the legislation was passed seventeen years ago, suggesting that substantive review of all its provisions is warranted.

The Review Panel has drafted this Discussion Paper to enable an informed discussion to occur on the current Victorian legislative model governing the pathology services industry. The Discussion Paper provides background information about the Act and regulations and identifies provisions that may impede competition. The Paper also describes the role of the Victorian Pathology Services Accreditation Board (PSAB) and that of the Commonwealth Government in the regulation of the pathology services industry.

A number of questions have been raised in the Discussion Paper. These are intended to stimulate broader thinking and discussion about the current Victorian accreditation<sup>1</sup> system and whether it serves the public interest, the legislation as a whole and whether there is a continuing need for State level regulation of the pathology services industry, and the form that any such regulation should take. Responses to the Discussion Paper should not be constrained in any way by the questions raised. Respondents should feel free to raise any additional matters relating to NCP requirements or to the provisions of the legislation more generally.

A key challenge for the Review Panel in preparing this Discussion Paper has been the lack of quantitative data to support various options for change that have been identified and uncertainty as to the size of the potential public risk associated with pathology services. In this context, quantitative data and methodological comments are particularly welcomed.

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<sup>1</sup> The term accreditation usually refers to industry-based quality assurance schemes that are non-statutory in nature. In this paper, the term accreditation is used to describe a statutory-based system of regulation of quality standards. The conferring of accreditation indicates to the user of a pathology service that the service meets the requisite standards for operation.

## 1.1 Submissions to the Review Panel

This Discussion Paper provides an opportunity for those who have an interest in the pathology services industry to assist in developing policy about the regulation of pathology services in Victoria. The Review Panel seeks submissions in relation to the questions and options raised in this paper and about other matters, which are not directly raised, but fall within the scope of the review. Submissions should be forwarded to:

Mr Don Nardella, MLA  
Chair  
Pathology Services Accreditation Legislation Review  
C/- Legislation Review Unit, Acute Health Division  
Department of Human Services  
17/555 Collins Street  
MELBOURNE 3000

Alternatively, submissions may be faxed to (03) 9616 7764 or emailed to milena.canil@dhs.vic.gov.au.

It should be noted that all submissions will be treated as public documents unless there is a clear request that a submission be treated as confidential.

## 1.2 Context of the Review

### 1.2.1 National Competition Policy

Following the inquiry into National Competition Policy (NCP) by the Independent Committee of Inquiry chaired by Professor Fred Hilmer (Hilmer *et al*, 1993), the Commonwealth and all States and Territories signed three agreements that comprise the NCP:

- the Conduct Code Agreement,
- the Competition Principles Agreement; and
- the Agreement to Implement the NCP and Related Reforms.

These agreements commit the Commonwealth Government and State and Territory Governments to implementing economic reform via a nationally consistent approach, acknowledging the diminishing economic significance of State and Territory boundaries and that, to improve the overall competitiveness of the Australian economy, Australia must act as a single, national market.

In its report, the Independent Committee of Inquiry (the Committee) stated that regulatory restrictions on competition pervade the Australian economy "...ranging from government sanctioned monopolies to licensing regimes and various restrictions on particular competitive conduct" (Hilmer *et al*, 1993:189). The Committee's report noted that these restrictions, which include diverse industry-specific and jurisdictional regulatory arrangements, can impose unnecessary costs on businesses, particularly those businesses that operate across borders (Hilmer *et al*, 1993; Harman and Harman, 1996).

The Committee's report proposed that to reduce these restrictions on competition, governments should adopt the principle that there should be no regulatory restrictions on competition unless the restrictions can be clearly demonstrated to be in the public interest. Consequently, the Committee recommended that governments review all existing

legislation for consistency with that principle (Hilmer *et al*, 1993). Under the NCP, governments have committed to such reviews. Accordingly, as part of this process, the Department of Human Services is reviewing, and where necessary reforming, all existing legislative restrictions contained in legislation that the Department administers. The guiding legislative principle of the NCP, which must be adopted in this review, is that legislation (including Acts, enactments, Ordinances or regulations) should not restrict competition unless it can be demonstrated that:

- the benefits of the restriction to the community as a whole outweigh the costs; and,
- the objectives of the legislation can only be achieved by restricting competition (Department of Premier and Cabinet, 1996a: section 3.8).

This guiding principle does not imply that competition objectives should take precedence over the achievement of public policy objectives. Instead, what must be established is whether legislative restrictions on competition contained in existing legislation remain necessary to the achievement of the original regulatory objective, given alternatives for achieving that objective.

To ensure that reviews are undertaken across all portfolios in a consistent manner, the Victorian Department of Premier and Cabinet has issued *Guidelines for the Review of Legislative Restrictions on Competition* (Department of Premier and Cabinet, 1996b). These guidelines provide the framework for the conduct of reviews and require that, at a minimum, legislation reviews consider the following:

- the objectives of the legislation;
- the nature of the restriction on competition;
- the likely effect of the restriction on competition and on the economy generally;
- the cost and benefits of the restriction and their balance; and
- alternative means for achieving the same result, including non-legislative approaches (Department of Premier and Cabinet, 1996b).

To meet the requirements of the NCP, the guidelines specify that:

- there must be a presumption against statutory intervention and the onus should be on the proponents of intervention;
- the direct costs of regulation should be borne by the immediate beneficiaries of the regulation; and
- information is important and ordinary market mechanisms should generally not be inhibited, subject to active enforcement of fair trading and other laws (Department of Premier and Cabinet, 1996b:32).

**Critical to this review, therefore, is the presumption from the outset against any statutory regulation that restricts competition. The onus is on the proponents of intervention to demonstrate that the benefits of restrictions on competition outweigh the costs to the community.**

The terms of reference for the review are contained in Appendix A.

### **1.2.2 Principles of good regulation**

While the requirements of the NCP determine the form of the present review to a considerable degree, it is also necessary to assess the existing regulation against widely held principles of good regulation. Such assessment will ensure that the review does not focus

solely on competition related issues but is also cognisant of the Victorian Government's wider commitment to implement regulatory best practices in the public interest.

Two main sources of such principles can readily be identified. First, the governing Council of the Organisation for Economic Cooperation and Development (OECD), in 1995, passed the *Recommendation of the Council of the OECD on Improving the Quality of Government Regulation* (OECD, 1995). The OECD Council is composed of the Ambassadors of each of the 29 Member countries and passes such recommendations by consensus. Thus, Australia has endorsed the principles contained in this recommendation. The recommendation contains a ten point 'reference checklist', covering conceptual and procedural matters, which is reproduced below (see Box 1.1).

**Box 1.1: The OECD Reference Checklist for Regulatory Decision-Making**

1. Is the problem correctly defined?
2. Is government action justified?
3. Is regulation the best form of government action?
4. Is there a legal basis for regulation?
5. What is the appropriate level (or levels) of government for this action?
6. Do the benefits of regulation justify the costs?
7. Is the distribution of effects across society transparent?
8. Is the regulation clear, consistent, comprehensible and accessible to users?
9. Have all interested parties had the opportunity to present their views?
10. How will compliance be achieved?

In conceptual terms, the key elements of these principles are that there should be a clear understanding of the regulatory objectives and a direct link between the regulation and the objectives (point 1), that the action proposed should be proportionate to the problem (points 2 and 6), that a regulatory proposal should be based on an explicit assessment of alternative policy tools and be judged the most effective (points 3 and 6) and that the regulation should be an effective response to the problem (point 6).

Second, these principles are reflected and amplified in the *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies*, adopted by the Council of Australian Governments (CoAG) in April 1995 and amended in November 1997 (CoAG, 1997). While the principles and procedural requirements contained in this document were developed in order to improve quality control over nationally uniform regulation, they have broad relevance and have been

endorsed by all Australian Heads of Government. The following is a summary of these principles.

### **1. Minimising the impact of regulation**

As a general rule, the burden of proof that a regulation is necessary remains with the proponents of regulatory action. That is, there is an initial presumption against new or increased regulation. Thus, regulation should be the minimum necessary to achieve the identified objectives. Assessment processes for the development of regulations should be scientifically rigorous including, where appropriate, a risk assessment process.

### **2. Minimising the impact on competition**

Consistent with the NCP obligations, accepted by all governments, relating to all new and existing regulation, regulation should be designed to have minimum impact on competition. In particular, barriers to entry, barriers to exit or barriers to innovation should be avoided.

### **3. Predictability of outcomes**

Regulation should have clearly identifiable outcomes and should generally use performance-based requirements in preference to detailed, prescriptive standards.

### **4. International standards and practices**

Regulations should be compatible with international standards wherever possible, in order to minimise impediments to trade. National standards should be consistent with Australia's international obligations in terms of international trade openness.

### **5. Regulations should not restrict international trade**

Regulation should not discriminate between domestic and imported products or between imports from different countries. Other countries' standards should be accepted as equivalent to Australian standards if they meet the objectives of Australian standards.

### **6. Regular review of regulation**

Regulation should be reviewed at intervals not exceeding ten years. This may be achieved through the use of 'sunset' provisions.

### **7. Flexibility of standards and regulations**

Specified outcomes should be able to be adjusted or updated as circumstances change. However, amendments should not lead to undue uncertainty and hence impose greater costs.

### **8. Bureaucratic discretion**

The exercise of discretion should be standardised so that discrepancies in decision-making are minimised and uncertainty is reduced. However, there should be flexibility to deal with exceptional or changing circumstances. There should also be transparency and procedural fairness.

In addition to these principles, the CoAG document identifies several 'features' of good regulation (CoAG, 1997). While these relate, in part, to technical matters connected with

the implementation and management of regulatory systems, it is appropriate to highlight several that are relevant to the current review process:

**(a) Minimising regulatory burden on the public**

Regulation should be the minimum necessary and non-regulatory alternatives should be explicitly considered.

**(b) Minimising the administrative burden**

Regulation should be designed in such a way as to minimise the impact of administration and enforcement on both regulators and the regulated. This is particularly important where different levels of government are involved.

**(c) Regulatory impact assessment**

Proposed regulation should be subject to a regulatory impact assessment process, which quantifies costs and benefits as far as possible.

**(d) Compliance strategies and enforcement**

Regulatory measures should contain compliance strategies that ensure the greatest degree of compliance at lowest cost. This should include ensuring regulatory brevity and clarity, public education and consultation and the choice of alternative regulatory approaches with compliance in mind. Incentive effects should be considered explicitly<sup>2</sup>.

***1.2.3 1995 Licence Simplification Program Review***

This current NCP review of pathology services in Victoria is wider than the review that was conducted in 1995 as part of the Victorian Government's Licence Simplification Program<sup>3</sup>. The 1995 review was designed to consider all licensing legislation from the perspective of reducing or eliminating the burden imposed by Commonwealth and State duplication of functions (Department of Health & Community Services, 1995). This current review will shift the focus from whether Commonwealth-State duplication of functions impose an administrative burden on industry to consideration of the purpose of the Victorian legislation, and whether the restrictions on competition contained in the legislation are actually necessary to achieve that purpose.

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2 This means that, in determining enforcement strategies, regard must be given to the size of the disincentives for non-compliance as well as factors such as the degree of 'acceptability' of non-compliance within the community. Where major gains from non-compliance exist, and/or there is a relatively low level of commitment to the regulations within the community, increased enforcement activity, such as more frequent inspections and higher penalties, is likely to be necessary to ensure adequate compliance.

3 In September 1993, the Minister for Small Business requested a review of the Victorian Pathology Services Accreditation Board as part of the Victorian Government's Licence Simplification Program. In February 1994, the Department of Health & Community Services established a Working Party to clarify the state of pathology services in Victoria and to determine the best possible accreditation system for the State. The terms of reference for the 1995 review are contained in Appendix B and include the examination of the functions and responsibilities of the Pathology Services Accreditation Board, the process of accreditation in Victoria, the functions and responsibilities of the relevant Commonwealth bodies associated with pathology services accreditation, and the process of accreditation in other States. A full list of the Working Party's recommendations is contained in Appendix C.

## 2. The Pathology Services Industry

### 2.1 What are Pathology Services?

The National Health Strategy (Discussion Paper Number 6) explains that pathology is a diagnostic and interpretive science concerned with "...disease processes and the demonstration of them" (Deeble and Lewis-Hughes, 1991:9). Pathology relies upon the detection of changes in the tissues of the body, including blood, and other body fluids to understand the causes of illness or assist in establishing the cause of sudden or unexpected death (<<http://www.rcpa.edu.au/docs/nonmembers/pathology/basis.cfm>>).

Currently, pathology is divided into seven different disciplines (or areas of activity) comprising six 'specialist' disciplines and a general discipline:

- Anatomical pathology, which is concerned with tissue diagnosis of disease using biopsy material taken from a living patient or at post-mortem, or small specimens of separated cells (including fluids and tissue smears);
- Chemical pathology, which involves detecting changes in a range of substances such as electrolytes, enzymes and proteins, in blood and body fluids and detecting and measuring tumour markers, hormones, poisons and therapeutic and illicit drugs.
- Genetics, comprising clinical cytogenetics (which is concerned with the microscopic analysis of chromosomal abnormalities) and molecular genetics (which uses DNA technology to analyse genetic mutations).
- Haematology, which is concerned with diseases that affect the blood and with the management of blood transfusion services.
- Immunology, which is concerned with the immune system and involves, for instance, analysing the ability of the immune system to identify and destroy agents that are foreign to an individual's blood.
- Microbiology, which is concerned with diseases caused by organisms such as bacteria, viruses, fungi and parasites.
- General pathology, which requires a familiarity with the preceding six disciplines rather than a detailed knowledge (<<http://www.rcpa.edu.au/docs/nonmembers/pathology/discipline.cfm>>).

Current Victorian legislation does not define pathology but instead describes a pathology service as:

*...a service in which human tissue, human fluids or human body products are subjected to analysis for the purposes of prevention, diagnosis or treatment of disease in human beings and includes any premises from which a service is conducted (section 3, Pathology Services Accreditation Act 1984).*

Although western medicine considers pathology as one of its basic disciplines, the Review Panel is of the view that the Act's description of *pathology services* facilitates a broader view of pathology, thereby including the interests of complementary and alternative medicine in the study of disease.

## **2.2 The Pathology Services Industry**

### **2.2.1 Industry Characteristics**

#### **Settings for Pathology Services**

For most people, pathology services begin and end with large, central laboratories that are identifiable in name and location of their 'shop-front' service (collection centre). A relationship with these laboratories generally arises by way of a referral, by a general practitioner or specialist, to a collection centre where a specimen is taken usually by a nurse or qualified medical technologist. From the collection centre the specimen is delivered by courier to the laboratory where the specimen is analysed and the results interpreted by a pathologist. The results are then returned to the referring practitioner and may include a recommendation from the pathologist that further investigations be undertaken. With the pathology results in hand, and information derived from clinical findings and perhaps results from other diagnostic tests, the treating practitioner determines and conveys to the patient the necessary course of action or inaction.

Settings for pathology services are however much broader than this mainstream view, as is the role of the pathologist in the delivery of patient care. There are instances where there is no role for a pathologist as some types of tests can be conducted by general practitioners who are able to provide a complete pathology service (collection of specimen, analysis and interpretation of results) within their practice. This negates the attendance of the patient at a collection centre or the forwarding of specimens to a central laboratory for testing and analysis by a pathologist.

Pathology services are also provided within hospitals whereby specimens are collected from the patient while either in an emergency department, an admitted patient (inpatient) or an outpatient, and then sent to either a specialised or general laboratory within the hospital or to an off-site laboratory. It is in a hospital setting where a pathologist is likely to have more of a direct role, as a member of a multidisciplinary team, in the management of a patient's care. However, even in hospitals there are tests that can be conducted without the involvement of a pathologist or a laboratory. Innovations in technology are enabling some testing to occur 'at the bed-side' where the sample is collected, analysed and the results interpreted effectively at the patient's side.

#### **Principal-Agent Relationship**

In the main, patients rely on the performance of pathology testing in laboratory-based settings. Whatever the setting for a part or the whole of a pathology service, as with other diagnostic services, such as medical imaging, pathology services can only provide information to inform the treatment of a patient rather than directly contributing to the patient's well being. This information, in most cases, is complex and can only be interpreted with specialist knowledge. Currently, there are few simple pathology tests that can be readily undertaken and results analysed by the layperson. While commercially available test kits for detecting pregnancy or monitoring glucose levels are included in this group, they are nonetheless tests that can be backed up by laboratory testing to confirm results.

Deeble and Lewis-Hughes (1991) consider the user of the pathology service as not being the patient but rather the health practitioner who requests the test. The patient, as Deeble and Lewis (1991) point out, pays for the service. As a result, there arises a "...rather curious position where the user does not pay and the payer cannot use the service"

(Deeble and Lewis-Hughes, 1991:12). In the main, the demand for pathology services eventuates from a principal-agent relationship in which a health practitioner (the agent) performs, requests and/or interprets the results of a test for a patient (the principal).

As in most other industries where consumption or use of a service is conditioned by principal-agent relationships (for example, financial or investment advice), one party in this relationship (viz. the agent) is invariably endowed with 'superior' information relative to the principal. Although an agent is expected to act in accordance with a set of professional codes or ethics, the agent may nonetheless behave opportunistically by exploiting the principal's 'ignorance' or inability to judge the quantity and quality of service provided. Over-servicing is an example of opportunistic behaviour that has attracted the attention of health policy makers in recent times.

### **Quality**

In addition to the reliance on the skill of the treating practitioner in interpreting results and applying that interpretation to an appropriate course of action, the patient also relies upon the skill of the practitioner collecting the specimen, the skill of the pathology service provider and the efficacy of equipment and reagents used in the collection, transport and testing process. Similar reliance is placed on the application and maintenance of quality assured systems that guarantee the integrity of each step in the provision of the pathology service.

However, according to the PSAB, "...pathology testing carries with it a certain margin for error..." (1994:23). Consequently, the patient is not in a position to know whether the collection, testing and interpretation of results have been performed competently nor is the patient necessarily aware of the degree of accuracy of the testing process and the potential for false positive and false negative results. To illustrate the potential for error to arise in pathology testing, Box 2.1 briefly discusses the recent inquiry into the under-reporting of abnormalities in cervical smear tests taken in Gisborne, New Zealand. It is important to be aware that the pathology laboratory at the centre of the Inquiry, while a participant in New Zealand's National Cytology Screening Programme (NCSP), was not subject to mandatory accreditation or quality assurance. In response to the recommendations of the Committee of Inquiry, various changes have been introduced for pathology services that provide laboratory and colposcopy services for the NCSP. These changes include requirements for laboratories to "...meet specific requirements in a range of areas including...accreditation, internal and external quality control...[and]...cytology and histology processing and reporting procedures" (<<http://www.csi.org.nz/media/moh-release1.htm>>).

Because of the complex and specialist nature of pathology services, the market does not provide patients with sufficient information for them to be able to judge the quality of service provision or even to choose amongst proficient service providers. Price differences, at least in terms of mainstream pathology testing conducted by Medicare remunerated providers, cannot be assumed as an indicator of quality. Generally, patients are satisfied to be guided in 'choosing' a pathology service provider by the health care practitioner that orders the test. Reliance on such 'guidance' arises from the view that the health care practitioner would be more knowledgeable about a pathology services' quality of service provision given the nature of the relationship between the health care provider and the pathology service. Nonetheless, the role of the health care practitioner must extend to providing patients with adequate information about the reliability of diagnostic testing and the potential for false negative and false positive results to occur.

**Box 2.1: The Under-Reporting of Abnormalities in Cervical Smear Tests—  
Gisborne, New Zealand, Cervical Screening Inquiry**

The under-reporting of abnormalities in cervical smear tests taken from women living in the Gisborne region of New Zealand initially came to light after extensive publicity about High Court proceedings taken by a patient against a medical practitioner. The patient concerned had developed cervical cancer in spite of a history of regular smear tests that did not indicate abnormalities. Following the diagnosis of cervical cancer and requiring a full hysterectomy at age 26, the patient successfully established a claim for medical misadventure before the Accident Compensation Commission and had a complaint filed against a Dr Bottrill upheld by the Medical Council. The patient's subsequent civil proceedings in the High Court against Dr Bottrill was based on her claim that the misreading of her cervical smear tests was negligent. Publicity about the nature of the High Court proceedings encouraged other women whose cervical smear tests had been read by Dr Bottrill to come forward (<http://www.csi.org.nz/report/>).

In response to mounting concern, the Health Funding Authority took action to have cervical smear tests read at Gisborne Laboratories, where Dr Bottrill practiced, re-read by Douglass Hanly Moir Pathology in Sydney. Gisborne Laboratories read as 'normal' the smear tests of 16 women who had developed cervical cancer. These same tests, re-read by Douglass Hanly Moir Pathology, indicated cervical cancer or high-grade abnormalities (<http://www.csi.org.nz/report/>). As a result of these findings and growing public concern, the New Zealand Health Minister appointed a Committee of Inquiry in October 1999 to determine whether there had been an unacceptable level of under-reporting of abnormalities in cervical smears in the Gisborne region of New Zealand prior to March 1996 (<http://www.csi.org.nz/report/>).

According to the report of the Committee of Inquiry, the reading of cervical smear tests is subjective and open to interpretation. "Pathologists accept that errors can occur and that occasionally a cervical smear test will be misread as a false negative or false positive" (<http://www.csi.org.nz/report/>, p. 17). Further, the Committee of Inquiry advises that false negative results (which fail to identify a pre-cancerous abnormality or cancer of the cervix) may arise because the smear was not properly taken or, if it was properly taken, none of the abnormal cells were included in the sample (<http://www.csi.org.nz/report/>). The Committee of Inquiry also explains that "cervical cancer is usually a slow-developing disease and in most cases the single under-reporting of a cervical smear test will not endanger a woman's health or life...However, if a series of cervical smear tests of a patient are under-reported the consequences for that patient can be dire as once the disease has progressed to cervical cancer the necessary treatment has a severe impact on the patient and its outcome is more problematic" (<http://www.csi.org.nz/report/>, p. 8).

The Committee of Inquiry's report raises the difficulty faced by health authorities and health professionals in distinguishing between the false negative tests that are an inherent feature of cervical screening and unacceptable under-reporting. According to the Committee of Inquiry, "until a pattern of errors, which suggests something worse than the accepted false negative rate comes to light, an unacceptable level of under-reporting is difficult to detect" (<http://www.csi.org.nz/report/>, p. 19).

Nonetheless, in terms of the Gisborne Inquiry, the findings of the Committee of Inquiry exposed a series of problems in relation to the delivery of cytology services in New Zealand between 1990 and 1996 and with practices at Gisborne Laboratories. In short, the Committee of Inquiry concluded that the Gisborne Laboratories:

- had no specialised division of labour for reading cervical smear tests;
- inadequate internal quality control including no organised correlation of biopsy results with cytology results;
- inadequate systems and procedures;
- no external quality control; and
- no accreditation with an independent quality control authority (<http://www.csi.org.nz/report/>).

Further, in terms of the Gisborne Laboratories' pathologist, the Committee of Inquiry found that Dr Bottrill's participation in continuing medical education was inadequate and that he had no awareness that the laboratory's practices put patients at risk (<http://www.csi.org.nz/report/>).

In relation to New Zealand's National Cytology Screening Programme, the Committee of Inquiry reported that:

- laboratories reading cervical smears were not required to follow quality control processes or be accredited with an independent quality control authority;
- government policies relating to laboratories involved in the cytology screening service were not well designed;
- the National Cervical Screening Register was not functioning optimally; and
- there were no performance standards for laboratories and no reliable data on the performance of laboratories (<http://www.csi.org.nz/report/>).

The Committee of Inquiry formed the view that, if those factors which the "Programme had lacked had been present, the practice of cervical screening at Gisborne Laboratories would have been improved or stopped. Either way the risk of unacceptable under-reporting would have been considerably reduced" (<http://www.csi.org.nz/report/>, p.9). Further, the Committee of Inquiry conceded that the under-reporting that occurred at Gisborne is evidence of a systemic issue for the National Cervical Screening Programme and that Dr Bottrill's practice cannot be seen as an isolated case (<http://www.csi.org.nz/report/>).

### **Financing and Service Provision**

In Victoria, as with the rest of Australia, the pathology services industry can be divided into two sectors: a public sector and a private sector. While the regulation of service provision in both sectors is similar, these sectors are distinct in terms of their source of financing and the proportion of the total amount of pathology work undertaken.

In terms of financing, the private sector generally relies on funds provided by the Commonwealth Government through Medicare for all pathology services that it provides. There are however exceptions and these include any pathology services provided by

alternative health practitioners and certain screening tests that are not included in the Medicare Benefits Schedule. In providing these services, private sector pathology service providers rely on patients (which may include the patient's employer or health insurance organisation) to fully meet service costs. Another exception is the funding of pathology services provided by private sector-operated, public hospital laboratories. In Victoria, funding for these services occurs through the casemix payment system and Medicare in the same manner that funding is provided for public sector-operated, public hospital laboratories.

For public sector laboratories, funding generally occurs through one of two processes. Funding for pathology services provided through public hospital laboratories depends upon the admission status of the patient—not the ownership status of the laboratory. Pathology services provided for public inpatients (admitted patients) are funded through casemix payments and other grants. For those patients who elect to be treated as *private* patients, pathology services are funded through Medicare (at 75 per cent of the scheduled fee) with the remaining cost being met by the patient's health insurance organisation and/or by the patient. In general terms, pathology services provided to public hospital outpatients (non-admitted patients) are funded through the Victorian Ambulatory Classification System. Where the outpatient department is conducted via a private arrangement (that is, the outpatient service is not a department of the hospital), funding for pathology services is through Medicare.

Other public sector providers include reference laboratories<sup>4</sup>. These laboratories are either fully funded by the Commonwealth Government, such as the National Serology Reference Laboratory, Australia; jointly funded by the State and Commonwealth Governments such as the Victorian Cytology Service or, majority funded by the State Government with additional funding from the Commonwealth Government for the conduct of specific tests as in the case of the Victorian Infectious Diseases Reference Laboratory.

Up-to-date, comprehensive data on service provision, by sector, is difficult to obtain and at best could only be estimated. In 1991, Deeble and Lewis-Hughes used several sources to estimate that "...about 59% of all Australian pathology services are provided by private laboratories and doctors and 41% by public authorities, mostly hospitals" (p.13).

The Commonwealth makes available data on pathology services for which Medicare rebates are paid (see Table 2.1). While the data does not account for all pathology services provided in Australia, as it excludes any service for which a Medicare rebate is not paid, the data does indicate that private sector pathology services are responsible for the provision of the majority of Medicare-funded pathology services (93 per cent of all services provided in 1999-2000).

There is not a single data set that can provide information on the number of pathology services provided for which a Medicare rebate is not paid (including the number of tests conducted by Medicare ineligible providers). While in Victoria the PSAB accredits all pathology services, irrespective of Medicare eligibility, it does not routinely collect any service utilisation data.

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<sup>4</sup> In general terms, reference laboratories undertake specialised and infrequently requested tests on behalf of other pathology service providers. Some reference laboratories are engaged by government to evaluate test kits and monitor their use, conduct quality assurance programs, and provide specialist information and training for other laboratories.

**Table 2.1 Medicare-Funded Pathology Services Provided, by Sector, by State/Territory**

	Number of Medicare-Funded Services					
	Public Sector Providers		% change	Private Sector Providers		% change
	1998–1999	1999–2000		1998–1999	1999–2000	
ACT	25,298	23,007	-9.06	Not available	Not available	
NSW	1,052,682	1,024,773	-2.65	10,375,551	11,253,900	8.47
NT	Not available	Not available		455	411	-9.67
QLD	397,824	422,647	6.24	10,542,837	11,968,732	13.53
SA	607,735	591,814	-2.62	711,619	724,627	1.83
TAS	2,598	2,120	-18.40	1,056,142	1,186,974	12.39
VIC	584,808	590,886	1.04	13,923,694	15,222,986	9.33
WA	300,616	306,435	1.94	13,108,078	14,124,413	7.75
TOTAL <sup>1,2</sup>	2,971,561	2,961,682		49,700,376	54,482,043	

- Notes: 1. In addition to 1998–1999 total services, 2,928,648 services were not readily identifiable as public or private from the available data. In addition to 1999–2000 total services, 1,317,719 services were not readily identifiable as public or private from the available data.
2. Overall total services provided in 1998–1999: 55,600,585. Overall total service provided in 1999–2000: 58,761,444.

Source: Health Insurance Commission, Canberra, January 2001.



# 3. Regulation of the Pathology Services Industry

## 3.1 The Development of Pathology Services Accreditation— an Overview

The growth in the demand for pathology services (which began in the late 1960s), rapid advances in technology and concerns of professional organisations about unacceptable practices by some pathology services, provided the impetus for calls for the accreditation of pathology service providers (National Pathology Accreditation Advisory Council (NPAAC), undated; White, 1996). By 1974, a review by the Commonwealth Government found that the cost of pathology services in Australia was rising significantly faster compared to the costs of other health services. The review recommended an accreditation scheme be established to curb the potential for abuse of services and to protect patients through good quality control and accurate interpretation of results, and to disseminate advice and conduct education programs (White, 1996).

A multi-party Working Group was convened to develop a detailed proposal for an accreditation scheme. The proposal subsequently received in-principle agreement at a 1976 Australian Health Ministers' Conference. In 1979, the National Pathology Accreditation Advisory Council (NPAAC) was established by Order in Council to develop nationally uniform standards for the operation of pathology laboratories and to encourage and coordinate the introduction of accreditation (NPAAC, undated; White, 1996).

Following the establishment of NPAAC, some time passed before Australian Health Ministers agreed that priority should be given to the establishment of pathology accreditation procedures in their respective jurisdictions. As a result, New South Wales passed its *Pathology Laboratories Accreditation Act* in 1981 and the *Pathology Services Accreditation Act 1984* was passed in Victoria (NPAAC, undated). The first members of the Victorian Pathology Services Accreditation Board were appointed in early 1985.

Only New South Wales and Victoria passed legislation requiring the accreditation of pathology services. As the New South Wales legislation was not proclaimed, Victoria was alone in the establishment of accreditation for pathology services. The lack of progress in this regard by the other States and Territories, and the findings of a 1985 Joint Committee of Public Accounts report on Medical Fraud and Over-servicing—which had identified areas of abuse in Australian pathology practice and recommended that Medicare benefits be payable only when pathology services are performed in an accredited laboratory—led the Commonwealth, in 1986, to introduce an Australia wide accreditation system for services seeking Medicare rebates<sup>5</sup> (National Association of Testing Authorities (NATA), undated).

A perusal of the body of legislation that exists in other States and Territories has not revealed any promulgated Acts dedicated to the accreditation of pathology services. Moreover, the Review Panel is not aware of any intention on the part of the Commonwealth to require, in the foreseeable future, States and Territories to introduce accreditation schemes for pathology services. Hence, Victoria remains the only State with its own statutory accreditation scheme for pathology services.

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<sup>5</sup> Given the slow progress made in the establishment of a national accreditation program, the Royal College of Pathologists of Australasia invited NATA to collaborate in launching a national program for voluntary accreditation of pathology testing services (NATA, undated).

As a consequence, a body corporate or an individual seeking to establish a new pathology service or operate an existing service, in Victoria, must comply with Commonwealth and Victorian pathology services legislation. Both jurisdictions accredit pathology services, inspect facilities, determine which range of tests can be performed and by whom and, have at their disposal a series of powers of investigation and inquiries.

Medicare rebates for diagnostic testing is the only factor that distinguishes whether both Commonwealth and State or State only accreditation will be applied to a pathology service.

## **3.2 Overview of the Scope of the Commonwealth's Legislation**

In terms of pathology services, the purview of the Commonwealth's *Health Insurance Act 1973* extends only to those services for which a Medicare benefit is sought. While the emphasis of this legislation is on regulation and control of costs—specifically to prevent the proliferation of pathology services and mitigate against the abuse of the Medicare payment system—it is also concerned with standards maintenance and quality service provision.

To attract a Medicare benefit, a pathology service must be:

- performed in a pathology laboratory (it must be an Accredited Pathology Laboratory (APL));
- provided by or on behalf of an Approved Pathology Practitioner (APP) (who must be a registered medical practitioner); and,
- performed in an Accredited Pathology Laboratory of which the proprietor (natural person, body corporate or 'government authority' such as a public hospital) is an Approved Pathology Authority (APA).

### **3.2.1 The Commonwealth Accreditation Process**

In order for a pathology laboratory to gain APL status, application (in the form of a submission and fee—see Table 3.1) to the Health Insurance Commission (HIC) must be made. A separate application for inspection of the premises must be lodged with the National Association of Testing Authorities (NATA)—see discussion below. Applications for recognition as an APP and APA must also be made to the HIC<sup>6</sup>.

Applicants in States and Territories other than Victoria must first seek 'provisional accreditation'. To do so, laboratories must have made application to NATA and have received a NATA application number. As 'applicants', laboratories are entitled to claim Medicare benefits but they must have undergone an assessment within a given period otherwise the NATA applicant status and HIC provisional accreditation will lapse. These laboratories are considered 'applicants' until they have successfully undergone assessment. In determining applications, the HIC, as delegate of the Commonwealth Minister for Health and Aged Care, takes into account matters such as:

- the location of the laboratory;
- the types of pathology services sought to be performed; and,
- whether such services will be performed by or under the supervision of an appropriately qualified person (Department of Health and Aged Care, 1998).

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<sup>6</sup> Until 1994 applications for approval as an APL, APP and APP were made to the Commonwealth Department of Human Services and Health (NATA, undated).

The Commonwealth Minister also takes into account the findings of an assessment of the premises, equipment and technical competence of laboratory staff. NATA acts on the Commonwealth's behalf as the primary inspection/assessment agency. The NATA assessment is conducted on the basis of nationally uniform standards established by NPAAC<sup>7</sup> and the NATA/RCPA<sup>8</sup> Medical Testing Requirements for Registration (Department of Health and Aged Care, 1998). Appendix D sets out further details about the Commonwealth accreditation process and the role of NATA and professional colleges in the accreditation process.

In terms of attaining APP<sup>9</sup> and APA<sup>10</sup> status, the Commonwealth's legislation provides, amongst other things, for an assessment of the fitness and propriety of the person. In relation to a medical practitioner seeking APP status, Commonwealth legislation specifies that the Minister shall have regard to matters such as the person's formal qualifications and experience, and the relationship of that person to those who will derive financial benefits from the conduct of pathology services.

The Commonwealth's Health Insurance Act also provides for the establishment and approval of Pathology Specimen Collection Centres. Pathology Specimen Collection Centres are operated and staffed by an APA and are engaged in the collection of samples for testing in APLs (<<http://www.health.gov.au/hfs/haf/docs/apcc.htm>>).

### 3.3 Overview of the Scope of the Victorian Legislation

Unlike the Commonwealth's legislation, the *Victorian Pathology Services Accreditation Act 1984* extends both to pathology services that are eligible for Medicare rebates, and to those services that are either ineligible or do not seek access to such rebates.

The objectives of the Victorian Act are to:

- ensure that proper standards of practice and technical procedures are observed routinely in pathology services;
- ensure adequate standards of record keeping in pathology services;
- encourage the use of safe working practices in pathology services and to discourage the use of unsafe or potentially unsafe practices; and,
- ensure that staff employed in pathology services have had adequate and appropriate training.

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7 NPAAC standards are non-prescriptive, general statements that facilitate more detailed standards to be published periodically; essential for an industry that undergoes constant changes in terms of technology and practice (White, 1996).

8 A formal agreement between NATA and the Royal College of Pathologists of Australasia (RCPA) ensures that a pathologist attends every laboratory assessment as part of the NATA assessment team. Additionally, the RCPA plays a significant role in the development of policy through NATA's Medical Testing Advisory Committee and the RCPA is regularly consulted by NATA for advice, for instance, on technical matters. RCPA also conducts quality assurance programmes for pathology laboratories (NATA, personal communication).

9 To obtain APP status, an appropriately registered medical practitioner must sign an undertaking, annually, that he/she will adhere to the legal requirements for the requesting, personal supervision, referral and billing of pathology services rendered (White, 1996).

10 Owners of laboratories must sign an undertaking, annually, that they will comply with legislative provisions governing the requesting of services, performance and billing of services rendered, financial relationships with employed APPs, business partnerships, bribery and advertising (White, 1996).

To facilitate these objectives, the legislation has established an accreditation system for pathology services and, supported by regulations, prescribes matters such as who can lawfully be in charge of a service, adequacy and qualification of staff, equipment and facilities, service standards and advertising.

Regulation of the Victorian pathology services industry is the responsibility of the Pathology Services Accreditation Board (PSAB). Appointed by the Governor in Council, the PSAB comprises nine members:

- one person representing the Government of Victoria;
- three pathologists nominated by the Victorian State Committee of the Royal College of Pathologists of Australia;
- three scientists each nominated by the Australian Association of Clinical Biochemists, the Victorian Branch of the Australian Institute of Medical Laboratory Scientists and the Medical Scientists Association of Victoria, respectively; and,
- two medical practitioners, one a member of the Royal Australian College of General Practitioners and the other a specialist physician nominated by the Victorian Branch of the Australian Medical Association.

The PSAB's functions include:

- accrediting and registering pathology services;
- making recommendations to the Minister on proposals for regulations pertaining to matters such as minimum qualifications required for the person in charge of each category of accredited pathology service and any person conducting tests, minimum standards required for the conduct of tests; and
- making recommendations to the Minister about which tests should be prescribed as exempted tests<sup>11</sup> and non-regulated tests<sup>12</sup>.

The Act also empowers the PSAB to hold enquiries, direct a proprietor to arrange for an inspection of the service to be conducted and, to arrange random, unannounced inspections. If it is found that a pathology service proprietor has failed to maintain adequate standards, the Act provides the PSAB with a range of powers including prosecution, issuing a written direction that a prescribed standard be met and cancelling or suspending accreditation.

### **3.3.1 The Victorian Accreditation Process**

Application for accreditation requires a submission and fee (Table 3.1) to be forwarded to the PSAB. For services seeking Medicare rebates, the application made to the PSAB (including the fee paid) is additional to that made to the Commonwealth. According to an earlier Departmental review (Department of Health and Community Services, 1995), "the process is very similar in the two jurisdictions but there are some minor differences" (p.7). For instance, the application form used by the Commonwealth is more complex and requires more extensive information than that used by the PSAB (Department of Health and Community Services, 1995).

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<sup>11</sup> An exempted test is a test that, on the PSAB's recommendation, the Governor in Council prescribes as exempted. As a result, such a test may be conducted at premises that are not accredited and be conducted by or under the supervision of a medical practitioner or a dentist in the course of the practitioner's or dentist's practice (section 30, Pathology Services Accreditation Act).

<sup>12</sup> A non-regulated test is an exempted test that, on the recommendation of the PSAB, the Governor in Council prescribes as a non-regulated test. The provisions of the Act do not apply to non-regulated tests (section 30A, Pathology Services Accreditation Act).

Once an application is lodged with the PSAB, it is considered at the next scheduled meeting. If the application is satisfactory, then the PSAB may grant 'deemed accreditation' under section 18A(1) of the Pathology Services Accreditation Act and the service may commence operating (PSAB, 1994). The 'deemed accreditation' status is similar to the 'provisional accreditation' status conferred by the Commonwealth.

According to the PSAB (1994), an inspection of a new service normally occurs within six to nine months of the granting of deemed accreditation. The PSAB (1994) explains that it would be futile to inspect a laboratory on the first day of its operations as, in the absence of testing, there would not be test results to examine, nor any quality control data to review and it would be difficult to judge the adequacy of staff.

NATA has been contracted by the PSAB to undertake inspections on its behalf—an arrangement similar to that which exists between the Commonwealth and NATA. In Victoria, the Royal Australian College of General Practitioners (RACGP) has also been appointed to inspect services where tests are performed by or under the supervision of a registered medical practitioner for patients of that practitioner. Consequently, in Victoria, these pathology services may choose whether they wish to apply to NATA or to the RACGP for an inspection to be conducted (NATA, undated).

The criteria for assessment of Victorian pathology services are based upon the requirements contained in the Pathology Services Accreditation Act and Pathology Services Accreditation (General) Regulations, NPAAC Standards and the NATA/RCPA Medical Testing Requirements for Registration. The assessment covers areas such as:

- the range and volume of work performed;
- staffing (including numbers, qualifications and expertise);
- specimen collection, identification and handling;
- suitability and maintenance of equipment;
- quality control;
- recording of results, the content and format of reports; and
- external quality assurance (NATA, undated).

The inspection of the laboratory begins with a preliminary discussion between representatives of the service and the assessment team. The inspection of the laboratory then proceeds in sequential order commencing with specimen collection and then may either proceed instrument-by-instrument or technique-by-technique (PSAB, 1994).

Following the inspection, the administrative process follows that for the Commonwealth accreditation process (outlined in Appendix D) with the only exception being that inspection reports for services that are either Medicare ineligible or do not seek Medicare rebates are not forwarded to the Commonwealth. Additionally, the reports emanating from the inspection of services by RACGP assessors are submitted to the PSAB with the laboratory's response (where applicable). Once a pathology service achieves full accreditation, it is still subject to inspections every two to three years. The process for the consideration of the reports emanating from these ongoing inspections follow the same process as those resulting from the inspection of new laboratories (PSAB, 1994).

**Table 3.1 Prescribed Fees for Applications Made Under the *Health Insurance Act 1973* and *Pathology Services Accreditation Act 1984***

Service category —Commonwealth	Commonwealth application fee <sup>1</sup> (\$)	Service category —Victoria	Victorian application fee <sup>2</sup> (\$)
GX (General)	2,500	G (General)	410
GY (General)	2,000		
B (Branch)	1,500	B (Branch)	410
M (Medical)	750	M (Medical Practitioner)	176
S (Specialised)	750	S (Specialised)	176
		U (Unspecified)	176

Notes:

1. Prescribed fees apply to applications for Accredited Pathology Laboratory (APL) status and for annual renewal of APL status. Fees of \$500 and \$1,500 must be paid to the Commonwealth for applications seeking Approved Pathology Practitioner and Approved Pathology Authority status, respectively. These fees are paid for initial applications and then annually.
2. Prescribed fees apply to applications for accreditation and annual renewal of accreditation.
3. Approved Pathology Specimen Collection Centres, which are not included in either the Commonwealth or Victorian service categories, are subject to an annual tax of \$1,000.
4. In addition to application and renewal fees, NATA requires a fee for an advisory visit and for each assessment. In Victoria, if a Category M pathology service chooses to be assessed a RACGP assessment team, a fee is required to be paid by the service to the RACGP.

*Source: Health Insurance (Pathology) (Fees) Act 1991, Health Insurance (Approved Pathology Specimen Collection Centres) Tax Act 2000, NATA—personal communication and Pathology Services Accreditation (General) Regulations 2001.*

### 3.4 Classification of Pathology Services

In the early 1980s, NPAAC devised a classification system for pathology services. The system comprised seven categories that varied according to the types of tests performed, the qualifications of supervisors and the extent of supervision (Department of Health and Community Services, 1995). NPAAC's classification system formed the basis for the categorisation system introduced into the Victorian legislation. The Victorian system differed primarily in that it included eight categories.

Significant changes have occurred in recent years in the pathology services industry. These have included advancements in laboratory technology, information technology and laboratory practice, the blurring of discipline boundaries and the amalgamation of private practices. In response, NPAAC has amended the categorisation of pathology laboratories. From 1 January 2000, the HIC began assigning laboratories to five new service categories, each defined on the type of person responsible to day-to-day supervision of the laboratory (see Appendix E for a description of the NPAAC categories).

Similar changes were proposed by the PSAB and made effective by Governor in Council on 26 February 2001. These essentially saw:

- Categories 4 and 7 being deleted;
- Category 1 and Category 2 services being classified as Category G (General);
- Category 3 services being classified as Category B (Branch);
- Category 5 services being classified as Category M (Medical Practitioner);
- Category 6 services being classified as Category S (Specialised); and
- Category 8 services being classified as Category U (Unspecified).

The latter category makes allowances for services which, although of a standard suitable to receive accreditation, may not fit the definitions of the other categories. A description of each of the new categories and comparison with the original eight categories is set out in Appendix F.

Table 3.2 presents an estimate of the number of services assigned to each of the Victorian Pathology Services Act's categories and compares these numbers with services assigned by the Commonwealth. According to this estimate, there are 42 more services accredited under the PSAB scheme than the Commonwealth scheme. While some of the differences between categories in terms of the number of services accredited by the two jurisdictions can be attributed to differences in classification, the difference in the overall number of services accredited arises because, as indicated earlier, services that either do not seek Medicare rebates for patients or are ineligible for such rebates are not required under the Commonwealth's *Health Insurance Act 1973* to seek accreditation. In Victoria however, these services must seek accreditation under the *Pathology Services Accreditation Act 1984*. The PSAB (1994) has suggested that the types of services that this could entail include:

- Services which only perform testing for screening purposes<sup>13</sup>, including State and Commonwealth funded screening services;
- Research laboratories<sup>14</sup>;
- Reference laboratories;
- Private laboratories willing to forego Medicare funding but capable of passing costs onto clients;
- Some medical practitioners' surgeries; and
- Red Cross Blood Banks (*sic*).

**Table 3.2 Pathology Services Accredited in Victoria, by Victorian and Commonwealth Categories**

Commonwealth Category	Commonwealth accredited <sup>1</sup>	Victorian Category	PSAB accredited <sup>2</sup>
GX	27	G	63
GY	22		
B	49	B	54
M	16	M	18
S	23	S	37
		U	7
<b>Total</b>	<b>137</b>		<b>179</b>

Notes:

1. Source: Health Insurance Commission, December 2000
2. Source: PSAB, List of Accredited Pathology Services in Victoria, September 2000

<sup>13</sup> A screening test is a test performed where there is no clinical indication that the test is required. Cholesterol screening is an example of a commonly performed screening test. Such testing may be conducted in pharmacies or shopping centres (PSAB, 1994:18; White, 1996). The coverage of this group can also be extended to sporting clinics which, for instance, may test urine specimen for banned substances and to health evaluation services such as those provided by health insurance funds and insurance companies.

<sup>14</sup> These laboratories may be located in Universities and use specimen taken from humans for research purposes.

A comparison of the number of services accredited under the Victorian and Commonwealth schemes supports earlier comments that the purview of the PSAB accreditation scheme is broader than that of the Commonwealth. However, whether the breadth of that purview provides sufficient grounds for the regulation of the pathology services industry by the State is a matter that underpins the review and will be considered more fully in the discussion that follows.

# 4. Competition Issues—Restriction on Competition

## 4.1 Introduction

As indicated earlier, this review is not limited to the issues of restriction on competition imposed by the legislation. Concerns for the Review Panel are broader and encompass the entire legislative framework and the role of the State in the regulation of pathology services *vis-à-vis* the Commonwealth's accreditation scheme for Medicare remunerated services. Nonetheless, the review is being taken in response to the Victorian Government's commitment to NCP and, as a result, it must be conducted in accordance with the *Guidelines for the Review of Legislative Restrictions on Competition* issued by the Victorian Department of Premier and Cabinet (1996b).

The Guidelines suggest a four-step approach to the review of legislation for NCP purposes, namely:

- Step 1: Describe the industry as it currently exists and the existing regulatory arrangements for the industry.
- Step 2: Identify the restrictions on competition in the existing legislation.
- Step 3: Demonstrate that the restriction is necessary to achieve the objective of the legislation and that there are no alternative means of achieving the desired outcome without a statutory restriction on competition.
- Step 4: Assess the costs and benefits to the community of the restriction on competition (Department of Premier and Cabinet, 1996b).

In the preceding chapters, this Discussion Paper has addressed the first step. Steps three and four will be addressed in the Review Panel's Final Report to Government. The Final Report will be drafted following the consideration of submissions made in response to this Discussion Paper. Step two will be addressed in this chapter. Accordingly, the focus of this chapter will be on the aspects of the Act and regulations that impose restrictions on competition. Subsequent chapters will address the issue of restrictions on competition in broader terms.

## 4.2 Identification of Restrictive Provisions

A review of the Pathology Services Accreditation Act and regulations has identified areas where the Act and regulations could be said to restrict competition—creating unnecessary barriers, stifling innovation, limiting consumer choice and reducing incentives to improve efficiency. The anti-competitive provisions contained in the legislation can be grouped under two key areas:

(a) barriers to entry:

- accreditation and categorisation of services;
- prohibition on purporting to be an accredited pathology service when not accredited;
- specification of minimum qualifications for persons in charge of a pathology service; and
- restrictions on who may perform certain tests at accredited pathology services.

(b) regulation of minimum standards and restriction on conduct

- specification of minimum standards for matters including staff, facilities, equipment, quality control and quality assurance and reporting;
- prohibition on advertising which is false or misleading, which compares services or deprecates another service or offers any reward or inducement; and
- prohibition on the performance of certain tests.

What follows is a brief discussion about issues raised by various provisions of the Act and the regulations grouped under these two key areas.

## 4.3 Discussion of Restrictive Provisions

### 4.3.1 Barriers to Entry

As explained earlier, the Pathology Services Accreditation Act requires that all pathology services conducted in Victoria be accredited by the PSAB and, upon granting accreditation, the PSAB may place a service into a category which the PSAB considers appropriate. It is an offence against the Act to conduct any tests that are not permitted to be performed in the particular category within which the accredited pathology service has been placed. It is also an offence against the Act to purport to operate an accredited pathology service if the service is not accredited or has not been granted deemed accreditation status by the PSAB.

#### Discussion Questions

- 4.1 Does the categorisation of services impose practical barriers to service delivery?
- 4.2 Does categorisation impede service expansion and exploring new business opportunities or achieving economies of scale?
- 4.3 Of what benefit to the public does the process of categorisation provide?
- 4.4 Has accreditation, under Victorian law, improved pathology service provision in this State? Is there any evidence to support either view?
- 4.5 Does the 'deemed accreditation' process impose any additional burden on pathology services?

While restrictions governing the ownership of pathology services were repealed from the Pathology Services Accreditation Act, the Act continues to restrict the position of 'person in charge of a pathology service' to a pathologist, a medical practitioner or a scientist<sup>15</sup>. The Act also limits the number of pathology services that a person can be in charge of to three. In addition, the *Pathology Services Accreditation (General) Regulations 2001* not only specify the minimum qualifications required of the person in charge of each category of pathology service but also specify the minimum qualifications for persons conducting the tests.

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<sup>15</sup> The Pathology Services Accreditation Act specifies that:

- A pathologist is a person who is a medical practitioner with a higher qualification in pathology recognised by the National Specialist Qualification Advisory Committee of Australia.
- A medical practitioner is a person who is registered under the Medical Practice Act
- A scientist is either:
  - (i) a person holding a degree or diploma obtained from a university or other academic institution in Australia after at least three years of full-time study in a prescribed science(s), or
  - (ii) a person who holds an associate qualification from the Australian Institute of Medical Laboratory Scientists granted prior to 1 January 1974 or,
  - (iii) a person holding a qualification from a university or other academic institution outside Australia which, in the Board's opinion is a qualification equivalent to that outlined in (i) or (ii).

#### **Discussion Questions**

- 4.6 Should qualifications for the 'person in charge' continue to be prescribed?
- 4.7 Should qualifications for people conducting tests continue to be prescribed?
- 4.8 Does prohibition on the performance of tests by those not appropriately qualified need to be regulated? What could be an effective alternative?
- 4.9 Should an upper limit be imposed on the number of pathology services a person can 'be in charge of'?
- 4.10 An issue raised in several reviews of various health practitioner registration legislation which may also be applicable in relation to the 'person in charge' of a pathology service, has been about practitioners who return to the workforce after a long absence and even registered practitioners who may not be keeping abreast of current developments. These reviews have considered imposing conditions on the renewal of registration of these practitioners, such as undertaking continuing education. Could a similar approach be taken with the imposition of conditions on the renewal of pathology services' accreditation? Would it be of value in minimising public risk?

#### **4.3.2 Regulation of Minimum Standards and Restriction on Conduct**

Contained in the regulations is a schedule which specifies matters such as requirements that must be met by services in terms of lighting, bench space, storage facilities, ventilation, water supply, emergency power, health and safety, equipment, quality control and reporting. The schedule contains a series of broad statements relating to matters that are set out in more detail elsewhere. For instance, various NATA publications pertaining to medical testing facilities set out requirements for the design and equipment requirement for a laboratory. These requirements are also supported by various Australian Standards and the requirement for premises to comply with the Building Code of Australia and Occupational Health and Safety legislation.

#### **Discussion Questions**

- 4.11 For pathology services seeking Medicare rebates, how does the content of the schedule add value to the relevant material available elsewhere, and in particular, that material used by NATA as assessment criteria?
- 4.12 For services that are ineligible or do not wish to seek Medicare rebates, is the body of information and standards that exist outside the Pathology Services legislation sufficient to ensure adequate design and attention to matters of safety and service provision?
- 4.13 Should such information be accompanied by a legislatively-based list of broad statements on safety, design, staffing, reporting, record keeping and the like?

### Controls on Advertising

The legislation stipulates a number of prohibitions on the advertising of pathology services. Advertising which is false or misleading and which compares services or deprecates another service is prohibited.

#### Discussion Questions

4.14 If the policy objectives are to safeguard the public in relation to pathology services and to mitigate the risks to health, how do legislative restrictions on advertising achieve these objectives?

### Exempted Tests

The *Pathology Services (Exempted Tests) Regulations 2001* list those tests which may be performed by or under the supervision of:

- a medical practitioner on behalf of a patient of that medical practitioner in the course of the medical practitioner's practice; or
  - a registered dentist on behalf of a patient of that dentist in the course of the dentist's practice
- whether or not the test is performed in an accredited pathology laboratory.

In terms of exempted tests, various concerns were expressed in response to the recently published Regulatory Impact Statement (RIS) that accompanied the proposed pathology services regulations (Department of Human Services, 2001). One submission to the RIS stated that the range of tests is limited and that general practitioners *only* should be able to conduct a broader range of tests such as cholesterol testing, to enable improved patient management (The Royal Australian College of General Practitioners (RACGP), 2001). The submission contended that by broadening the list of tests, savings to consumers would be realised through the convenience of not having to attend a pathology service. The submission added that the health system would also benefit, as Medicare would not need to pay a collection fee to a pathology service provider.

Another submission was received in response to the RIS that proposed to reduce the number of tests listed as exempted. The submission suggested that some tests—in particular, differential white cell counts and screening of blood film—are not simple screening tests. Tests such as these, it was argued, have far reaching clinical importance in diagnosing such diseases as some malignancies, leukaemia and lymphomas and blood cell diseases. The submission held that these tests should be regulated and conducted by qualified personnel (Austin & Repatriation Medical Centre—Network Pathology (ARMC), 2001).

#### Discussion Questions

4.15 Would changes to the types of tests that are currently exempted favour one group of health service providers (in this case general practitioners) over another?

4.16 What are the implications for public safety of having tests exempted from being conducted in accredited laboratories? Could other safeguards (other than accreditation) be applied?

# 5. The Need for Regulation?

## 5.1 Introduction

The Victorian system of accreditation of pathology services can be described as a form of ‘business licensing’ with the accreditation (effectively, the licence) providing an authority to operate the business. Licensing schemes, which impose a barrier to entry into an industry and establish parameters within which businesses must operate, are usually implemented because of problems or perceived problems in the way in which markets have operated in the past (Department of Premier and Cabinet, 1996b). Business licensing generally aims to reduce the incidence of problems by preventing problem traders from gaining access to the industry (or in some cases removing them from the industry).

The current Victorian legislation was developed and introduced in the early 1980s in response to Australia’s Health Ministers’ agreeing that statutory mechanisms for the accreditation of pathology services be introduced by each State and Territory. A compulsory accreditation scheme was seen as necessary to curb the potential overuse of services and to protect patients from poor quality practice.

Since the commencement of the Victorian legislation in the mid-1980s, wider health industry developments, which impinge on the pathology services industry, have occurred. Technological developments have advanced the breadth and sophistication of clinical care, including pathology testing, consumers (patients) have become increasingly aware of their rights to information and they have become more prepared to question decisions made by health practitioners. Formal avenues for the redress of consumer complaints and concerns have become more widely available. Over the same time the pathology services industry has grown in its net worth and has become increasingly dominated by large, private sector organisations, and the Commonwealth has introduced an Australia-wide accreditation mechanism for Medicare remunerated pathology services.

In light of these developments, the Review Panel considers it necessary to review the Victorian pathology services legislation from a broader perspective, rather than solely focussing the review on specific provisions within the legislation that may be deemed anti-competitive. Consequently, the Review Panel intends to explore whether:

- the legislation serves the public interest in terms of safeguarding quality standards and practice,
- the Victorian pathology services legislation as a whole or in part imposes restrictions on competition in the pathology services industry; and
- there are alternatives to the legislation which could be relied upon to achieve the same objectives as the legislation.

Mindful of the principles of good regulation discussed earlier in this paper, in considering whether a State-based accreditation regime for pathology services is necessary, the Review Panel has posed a series of key questions (see Box 5.1). As these questions are fundamental to the broader review, they also underpin a number of other ‘Discussion Questions’ that have been raised throughout this Discussion Paper. The Review Panel welcomes any responses or comments in relation to these questions.

### **Box 5.1: Key Questions for Consideration**

- **Is the Victorian Act consistent with the principle of minimum necessary regulation and the presumption against regulation?**

*Given that most pathology services are accredited nationally and that no other State or Territory has, or has ever had, an accreditation regime, can the Victorian Act be consistent with the principle of minimum necessary regulation? If a presumption against regulation is adopted, can the performance of the Victorian Act in practice satisfy the test of ensuring that its benefits justify its costs?*

- **Does the problem that the Act attempts to address pass the test of “materiality”?**

*The OECD checklist (see Chapter 1) asks if regulation is justified. This recognises that regulation has costs and imposes risks. There are also limits to the scope and extent of government action. Thus, the size of the identified problem must be sufficient to justify intervention. It is not sufficient merely to identify a potential harm. Does the problem that the Victorian Act attempts to address pass this test of materiality?*

- **Is the Victorian accreditation scheme consistent with the principle of minimising the regulatory burden?**

*Could other approaches to assuring the quality of pathology services in Victoria achieve acceptable outcomes while being less costly and less burdensome than the current accreditation scheme? What other approaches would be feasible? Could an accreditation system be designed that would be less burdensome than the current system, for example by being restricted to those services not accredited by the Commonwealth?*

- **Does the Victorian regulation take full account of incentive effects?**

*The principles (see Chapter 1) note that incentive effects should be fully considered. It is arguable that most pathology services that are outside the Commonwealth accreditation scheme face strong incentives towards maintaining high quality in the absence of regulation. To what extent does this obviate the necessity for the Victorian accreditation process?*

- **Do the benefits of the Act justify its costs?**

*Given the presumption against regulation, there must be a clear demonstration that regulatory benefits justify the costs involved. Is there any strong evidence that the functioning of the Victorian system of accreditation has led to this outcome? What have been the key benefits attained to date due to the existence of the Victorian legislation? To what extent can these be quantified?*

## **5.2 Materiality**

An important perspective on the question of whether regulation is needed is the question of “materiality”. That is, is the size of the problem that the regulation attempts to address sufficient to justify regulatory intervention? This question of materiality is implicit in the principles of good regulation, discussed in Chapter 1. Both the CoAG principle of ‘minimum necessary regulation’ and the OECD question ‘is regulation justified’ are based on the benchmark of materiality. Its importance is twofold.

First, there is an almost limitless range of possible regulatory interventions, each of which could be expected to provide some direct benefit, by reducing a risk of harm of some sort. However, the practical ability of government to regulate is clearly constrained—both by the limits of its own resources and by the negative impacts on the economy of an over-abundance of regulatory requirements. Thus, governments must be regulatory ‘optimisers’, limiting their regulatory interventions and choosing the most effective areas in which to intervene.

Second, regulation itself involves risks. Its effects on markets and behaviour are generally not fully foreseeable and unanticipated negative impacts frequently arise. This can be particularly true over the medium term as the dynamic impacts of a regulatory intervention come into play. Such effects can mean that the net effects of regulation can be negative, overall. However, once introduced, regulation is generally difficult to remove or reform due to the presence of strongly motivated vested interests.

In considering the question of materiality in relation to pathology services accreditation, the issue of practice in other Australian jurisdictions must be prominent. First, the passage of the Victorian legislation in 1984 pre-dates the adoption of an accreditation scheme at the Commonwealth level. The circumstances of its adoption were that it was assumed that each State and Territory would adopt equivalent accreditation requirements. Therefore, the current circumstances are clearly different from those originally envisaged. Given that no other State or Territory has subsequently adopted an accreditation scheme, it is clear that the Commonwealth scheme has largely supplanted the initial notion of equivalent State/Territory-based schemes. This, in turn, has meant that the Victorian scheme has necessarily ‘converged’ to a large degree with the Commonwealth scheme.

Given these factors, the major impact of the Victorian accreditation scheme would appear to be upon that subset of service providers that are not covered under the Commonwealth’s requirements. This represents between 20 and 25 per cent of the number of service providers, a large proportion of which are relatively small-scale businesses.

A second consideration is that of whether there are other reasons for the maintenance of high standards by service providers that would continue to operate in the absence of an accreditation scheme. One such incentive, which is likely to be important to many providers, is that the results of their pathology tests function as ‘inputs’ to other activities that they undertake. This suggests that poor performance in carrying out pathology tests would be expected to have a negative impact on their other activities and, at the least, would constitute poor business practice. This seems likely to be the case with many of the categories of service provider that are not accredited under the Commonwealth scheme, such as research laboratories and reference laboratories.

A third question is whether there are means by which consumers (whether patients or health care providers) of pathology services can exercise choice in ways that would lead to improved quality. In contrast to the early 1980s, when the legislation was under development, pathology services, like other laboratories and, indeed, the economy generally, are highly likely to have adopted external quality assurance processes. These quality assurance processes seem to be increasingly seen as essential marketing tools and, in line with increasing consumer expectations, they have been adopted. To the extent that this is the case, it is likely that quality assurance requirements can function as a means by which consumers—even at the individual level—become able to exercise judgement as to the likely quality of a pathology service.

All of these considerations tend to point towards a conclusion that the potential benefits of a Victorian accreditation scheme are somewhat less than would have been the case at the time of its adoption. This does not necessarily imply that such a scheme will now fail the test of 'materiality'. However, it does suggest that evidence must be adduced to show that the test of materiality is passed and that the legislation thus continues to be appropriate and relevant.

### **Discussion Questions**

- 5.1 Does the Victorian accreditation regime provide substantial benefits in respect of pathology services that are also accredited by the Commonwealth? If so, what are these?
- 5.2 What sectors of the pathology services industry would, if not subject to State-based accreditation, be likely to perform unsatisfactorily? Why would market disciplines, such as those discussed above, be likely to prove insufficient?
- 5.3 To what extent has Victoria gained material benefits vis-à-vis other Australian States/Territories as a result of its accreditation system? Is there any objective evidence for the existence of such benefits?

## **5.3 Protection of the Public**

The Victorian Act does not explicitly state that it has as a purpose to protect the public. However, as noted earlier, the Act's principal objective is to ensure that proper standards of practice and technical procedures are routinely observed in the conduct of pathology services. Thus, implied in this objective is that the legislation serves to protect the public from risk associated with the conduct of pathology testing. In addressing whether the legislation is indeed appropriate and justifiable in the public interest, a risk analysis should be undertaken. Such an analysis would involve an appraisal of the current level of risk to the population due to practices in pathology testing and determining:

- the reduction in risk due to the legislation;
- whether the legislation is the most effective means available to deal with the identified risk; and
- whether there is an alternative use of available resources which will result in greater overall benefit to the community (Department of Premier and Cabinet, 1996b).

However, as indicated earlier, little quantitative data is available to support any proper analysis of risk. In the absence of such data, judgements must be made about the level of risk posed by pathology testing (including specimen collection and laboratory analysis), interpretation of results and communication of these results to patients. Moreover, inherent in many forms of pathology testing are margins for error. Regulation cannot address this risk directly. All that regulation can do is assist in fostering acceptable practice and, possibly, encourage the uptake of new, improved testing technologies that may have reduced margins for error.

### **5.3.1 Level of Public Risk—a Qualitative View Point**

The principal concern of the Review Panel is thus to ensure that consumers of health services are adequately protected against poor standards of pathology testing.

Along the chain of actions from specimen collection to interpretation of test results and resultant action or inaction taken by the health care provider, there are many points at which error can occur. Pathology is not an exact science. Error may result from the techniques used in collecting and preparing specimens, labelling of specimens, and from their inappropriate storage and transport. At the laboratory, the equipment used may be incorrectly calibrated or reagents may be of dubious quality. As mentioned earlier, the technology underpinning particular tests may be the source of random error, contamination of specimens may occur or even the proficiency of the person undertaking the tests may be questionable. Interpretation of results by pathologists and health care providers also introduces further potential for error.

Neither the user of the health service (the patient) nor the user of the pathology service (the health care provider) is in a position to judge directly the proficiency of the pathology service or know whether the pathology service provided relevant and accurate information to inform the action or inaction of the health care provider. Similarly, in cases where the pathology testing has been undertaken by the consumer's health care provider, the consumer is none the wiser about the reliability of the information informing the resultant course of action or inaction. It is acknowledged however, that where a pathology service conducts tests for the health care provider, that health care provider is in a better position than the patient to identify poor pathology practice over a period of time and thus is better equipped to take some form of action. The Review Panel is of the view that this factor is significant in market self-regulation and will be raised again in chapter 7.1 as an alternative to statutory-based regulation of the pathology services industry.

## **5.4 Occupational Health and Safety Considerations**

The Act has, among its stated objectives, a desire to encourage the use of safe working practices in pathology services and to discourage the use of unsafe or potentially unsafe practices.

This concern with the occupational health and safety aspects of the functioning of pathology services extends to extensive regulation of the premises and equipment required to be provided. Requirements contained in the regulations relating to matters such as storage facilities, bench space, emergency power, water supply and staff amenities all appear to be at least partially concerned with occupational health and safety. The Act, having been passed in 1984, slightly predates the commencement of a major overhaul of occupational health and safety (OH&S) legislation carried out in Victoria during the 1980s and 1990s. This overhaul began in 1985 with the passage of the Occupational Health and Safety Act.

The changes in OH&S legislation were fundamentally concerned to provide an overarching set of controls, based on general duties applicable to employers and employees in all workplace circumstances. This objective is expressed in Section 21(1) of the Occupational Health and Safety Act 1985, which states that:

*An employer shall provide and maintain so far as is practicable for employees a working environment that is safe and without risks to health.*

The adoption of this approach, based on general duties, has led to the streamlining and rationalisation of legislation in this area, with many specific Acts effectively being replaced by the Occupational Health and Safety Act. A similar rationalisation of subordinate legislation has also occurred.

Given these changes, an important issue in this review is the continued relevance of those parts of the legislation relating to pathology services that deal with OH&S matters. The question necessarily arises as to whether there continues to be a need for OH&S regulation to be contained in legislation relating to specific types of workplace, in the presence of a generally applicable set of controls.

A relevant comparison in this regard might be the situation of other biological laboratories, which are not subject to specific OH&S controls, despite the fact that they may deal with similar matter and pose similar risks to their employees to those posed by pathology services.

Even if it is concluded that pathology laboratories pose particular OH&S risks that are sufficiently severe as to require specific regulation, it does not follow that this should be undertaken through an Act devoted solely to pathology services. An alternative that would merit consideration is that of making specific provisions under the OH&S Act. Section 55 of the Act allows for the development of Codes of Practice for the purposes of

*...providing practical guidance to employers, self-employed people, employees, ...or any other person who may be placed under an obligation by or under this Act.*

Section 56 of the Act sets out the status of Codes of Practice. In effect, non-compliance with a relevant Code is deemed, in any court proceedings, to constitute prima facie evidence of non-compliance with the duty or requirement of the Act in question. Thus, a Code of Practice constitutes a powerful quasi-regulatory tool.

Given these considerations, it is clear that the adoption of a Code of Practice, which the Victorian WorkCover Authority would develop with the Department of Human Services, would constitute a feasible option in the event that specific OH&S regulation of pathology services was considered to be needed. Given the intention of the OH&S legislation to cover the field, thereby applying consistent standards and approaches, there may be strong grounds for preferring such an approach.

#### **Discussion Questions**

- 5.4 Given the existence of overarching OH&S legislation, passed since the introduction of the Pathology Services Accreditation Act, is there a continuing need for OH&S matters relating to pathology services to be regulated specifically?
- 5.5 If there is such a need, what is the nature of the risks specifically related to pathology services that would justify such regulatory action?
- 5.6 If there is such a need, is it appropriate for such matters to be dealt with in any specific pathology regulation that may continue to exist, or would a Code of Practice or other instrument under the OH&S Act be more appropriate?

## **5.5 The Appropriate Intervention?**

In evaluating whether the maintenance of a State-based accreditation regime for pathology services, or any State intervention at all, is necessary, it is important to review the current legislation and requirements for accreditation. The discussion that follows will examine the performance of the current legislation. The discussion will then explore several existing alternative mechanisms that could be used to achieve quality standards in the pathology services industry.



# 6. The Performance of the Existing Legislation

## 6.1 Introduction

As noted earlier, the NCP agreements impose two fundamental requirements with respect to legislative reviews. These requirements are that restrictions on competition should be retained only where there are net benefits to the community as a whole accruing from the restriction and that there are no means other than restricting competition (or means that are less restrictive of competition) that would allow these benefits to be attained.

A number of means of estimating the benefits of the legislation can be identified. First, indicators of the quality of pathology services provision could be compared in order to measure directly whether standards have improved since the adoption of the accreditation regime. Secondly, indicators of the quality of pathology services in Victoria could be compared with their equivalents in other States/ Territories (that are either not captured under the Commonwealth accreditation regime or are subject only to Commonwealth accreditation) to determine whether the quality of pathology services is higher in Victoria than elsewhere in Australia. Thirdly, indirect indicators of the effectiveness of the accreditation system could be identified and assessed.

Of these possibilities, the first two are superior to the third, in that they involve direct measurement of the outcomes of the system, rather than a reliance on indirect indicators. However, a number of difficulties arise in respect of their use.

If comparison of the performance of the pathology industry over time did indicate clear improvements, these may well be due to factors other than the introduction of accreditation. Additional evidence would be needed in order to infer the likely contribution of the accreditation process per se. Moreover, the task is further complicated by the need to separate out the effect of the Victorian accreditation process from that of the national process. The likelihood of achieving this in practice is considered minimal.

Given this, comparison of the performance of the Victorian pathology industry with that of its counterparts in other States/Territories could be a more feasible means of determining the benefits of the accreditation system. As Victoria is the only jurisdiction to have implemented its own accreditation system, any observed differences between pathology performance in Victoria and in other States/Territories might be attributable to the accreditation system.

Performance data that might indicate differences in performance could include both technical and financial indicators. Included in the former category would be indicators of the accuracy and timeliness with which tests are conducted. The latter category would include the pricing of a range of pathology services. No significant data is currently available to the Review Panel in respect of either of these areas.

### **Discussion Questions**

- 6.1 Is it feasible to measure differences in the performance of the Victorian pathology industry and that of other States/Territories?
- 6.2 What indicators would potentially be usable to determine whether there were significant differences between the performance of Victorian pathology services and those of other States/Territories?
- 6.3 Do you possess, or are you aware of, any data relating to these indicators?
- 6.4 Are you aware of any evidence to suggest that the Victorian pathology industry achieves superior performance to that of other States/Territories? If so, can this be linked to the existence of the accreditation system?

## **6.2 Indirect Indicators of Performance**

Notwithstanding that indirect indicators of performance are less preferable than direct indicators, it must be acknowledged that the major data available to the Review Panel at present is of this kind. The following summarises the data collected to date and its implications in terms of demonstrating benefits attained as a result of the accreditation system.

In essence, it is assumed that data regarding the operations of the PSAB since March 1990 (when it commenced accrediting pathology services) can provide indications of the likely extent of the problems that might otherwise have gone uncorrected. Evidence of the impact of the accreditation system on the market for pathology services can be gleaned from the incidence of refused applications for accreditation, complaints received, investigations undertaken and successful prosecutions launched.

### **6.2.1 Accreditation**

At the time that accreditation was commenced, applications were received from a wide variety of sources. Among these were a significant number of applications from naturopaths and community health centres. Neither naturopathy services nor community health centres were accredited at that time.

In assessing the applications of naturopaths, the PSAB investigated the studies undertaken by practitioners and determined that they did not satisfy the Act's definition of 'pathology services'. Hence, it was concluded that naturopathy services were ineligible for accreditation.

In the case of community health centres, it is understood that the majority withdrew their applications following direction from the PSAB that they would be required to meet the regulatory requirements for the establishment and conduct of pathology services if they wished to continue providing health-screening services. In this instance, therefore, there was no theoretical barrier to accreditation. Rather, there appear to have been decisions on the part of the individual applicant centres that the costs of meeting the accreditation requirements were too great to be justifiable, given the nature of their proposed operations.

The accreditation process prevented practitioners in these two areas from describing themselves as pathology services. The effects of this appear to be different. In the case of

naturopathy, there can be considered to be an impact on consumer information available in the market. Arguably, confusion as to the nature of the services to be provided was averted by the effective prevention of the promotion of such diagnostic services as 'pathology services'.

In the case of community health centres, it is understood that the effect, at the time, was to prevent the conduct of a small range of simple screening tests, such as cholesterol monitoring. The practical effect of this is more difficult to determine. While the intended effect may have been to ensure that even such simple tests were carried out in more tightly controlled conditions, it is foreseeable that, for reasons of increased cost and reduced convenience, the number of such tests conducted could have been reduced. This, in turn, may have led to negative health outcomes.

Since the resolution of these issues during the first year of accreditation there have been no known instances in which an application for accreditation has been rejected by the PSAB. This apparently reflects the approach to accreditation taken by the PSAB. That is, the PSAB seeks to ensure that accreditation requirements are well understood by prospective applicants by encouraging informal preliminary enquiries to be made, rather than formal applications, where there is significant doubt that an application would be approved.

As the number of cases in which prospective applicants have been rejected at this 'informal inquiry' stage is not known, it is not possible to conclude with certainty whether the accreditation process continues to restrict practitioner numbers or affect quality.

### **6.2.2 Complaints**

The PSAB has received a total of 22 complaints against pathology services in the ten years since the commencement of accreditation. These complaints have been relatively evenly distributed from year to year, with a peak of six complaints received in 1998 and no complaints received in 1997.

These data might be taken to indicate that, from the earliest days of the accreditation regime, there has been little dissatisfaction with the quality of pathology services. However, the PSAB has argued, in its submission to the 1995 review of the accreditation system, that

*...the fact that relatively few complaints are received against pathology services does not necessarily indicate that their standards of operations are beyond reproach. But, rather, it is a reflection of the weakness of the complaints process as a weapon in detecting the practice of substandard pathology (PSAB, 1994: 23).*

According to the PSAB, this is due, in part, to the indirect relationship between the pathology service provider and the ultimate consumer of the service (that is, the patient) and the existence of an information asymmetry between the patient, the health care practitioner and the pathology service provider. Consumers (in this instance, patients), according to the PSAB, "...are not in a position to know whether a test was performed competently or not" (1994:23). Further, it is generally acknowledged "...pathology testing carries with it a certain margin for error..." (PSAB, 1994:23) and, as a consequence, an incorrect test result cannot necessarily be taken as evidence of poor practice on the part of the pathology service provider. For these reasons, the ability of individual consumers (patients) to make specific complaints about pathology services is minimal.

Further, if patients do have complaints about, for instance, the timeliness of service provision, cost of service and accuracy of testing, it is likely that these complaints will be made to the health care practitioner. The subsequent referral of these complaints to the pathology service provider may not occur given the possibility of significant disincentives to do so—such as working or commercial relationships. Given the lack of any statutory requirement for health care practitioners to record and refer complaints to a body, such as the PSAB, this may impede the resolution of patients' complaints and adds to the inability, at a broad level, to ascertain the level of patient satisfaction or dissatisfaction with the quality of pathology services.

In its submission to the 1995 review, the PSAB explained that prior to its establishment, there did not exist in Victoria a body specifically dedicated to the handling of complaints in relation to pathology services (p.23). The PSAB further explained that while the Victorian Health Services Commissioner (HSC) was able to mediate in relation to complaints about fees charged by pathology services, the HSC was without "...legal backing...[or]...expert staff to investigate and resolve complaints involving substandard or unsafe testing" (1994:23).

The Review Panel acknowledges that the Office of the HSC may not have the same level of in-house expertise, relating to pathology services, as a body that has been specifically formed for the purpose of regulating the pathology services industry. However, the HSC can (and does) access expert opinion to assist in its dealings with a range of complex complaints. It is likely, therefore, that the HSC would access expert opinion in relation to complaints about pathology services rather than needing to rely on in-house expertise. The Review Panel does however accept that while the HSC operates within a statutory framework with wide powers of investigation, unlike the PSAB, the HSC is limited in the application of sanctions.

Nonetheless, in terms of the infrequency of complaints being made to the PSAB, the Review Panel is concerned that the PSAB does not have a similar high public profile as the HSC; although the PSAB is well known within the pathology services industry. Hence, the lack of ease of being able to complain is compounded by the lack of knowledge of where to lodge a complaint. Of the 22 complaints that have been made to the PSAB, the Review Panel understands that industry members rather than individual patients have made the majority of these complaints. While this may be attributed to the indirect relationship between the pathology service and the patient, and the existence of information asymmetry, it may also be indicative of the PSAB's lack of public profile.

Finally, the complaints data do not reveal a declining trend in complaints, as might be expected over time if an accreditation system were acting to improve practice in an industry. Further, the data do not indicate that the investigation and resolution of complaints by the PSAB constitutes a major activity by which quality control is exercised. However, given the reservations noted above, and the low initial incidence of complaints, these observations must be treated with caution.

### ***6.2.3 Inquiries, Investigations and Directions to Comply***

The PSAB has conducted a total of three inquiries into pathology services in ten years. These occurred in 1991, 1996 and 1999. The first related to the failure of a pharmacy to apply for inspection and resulted in a six-month suspension of its accreditation. The remaining two inquiries related to the failure by pathology services to comply with regulatory requirements relating to the direct supervision of the performance of pathology

tests. In both cases, formal directions to comply were issued by the PSAB and service providers complied. However, in the most recent case, the pathology service sought judicial review of the appropriateness of the PSAB's direction (see Box 5.1). In light of the current review of the legislation, the pathology services provider withdrew the litigation against the PSAB and both parties agreed to bear their own costs.

In light of the PSAB's activity in relation to inquiries and investigations, exercise of these powers do not appear to have functioned as a major mechanism for improving or maintaining the standards of practice in the pathology industry.

**Box 6.1: Supervision of Staff—Conflicting Views and the Need for Clarity**

In September 2000 the Department of Human Services learned that a category G pathology service had sought judicial review of a PSAB direction relating to the supervision of staff. The pathology service proposed to provide supervision of staff performing pathology testing after hours by means of an appropriately qualified pathologist who would be able to answer telephone queries and view images transmitted over the Internet. The PSAB was of the view that such supervision did not amount to 'direct supervision' as required by regulation for that category of pathology service. The PSAB directed the pathology service to comply with the regulations.

The Victorian Pathology Services Accreditation (General) Regulations 2001 specify that:

*There are no prescribed minimum qualifications required for a person conducting tests in a Category G...pathology service if the test is performed under the direct supervision of a medical practitioner, a pathologist or scientist who –*

- (a) is qualified in the relevant division of pathology; or*
- (b) has conducted tests of that kind for an aggregate period of at least one year during the 5 years before commencement of the supervision.*

The Commonwealth accreditation scheme, under which the pathology service is also accredited, provides that, for a category GX or GY service, "...a supervising pathologist or senior scientist must usually be present during normal working hours, and available for telephone (or other electronic) consultation at other times" (principle 9(3), Health Insurance (Accredited Pathology Laboratories—Approval) Principles 1999). The Commonwealth's principles also require that the person directing and in control of the laboratory ensures that:

- supervision, as prescribed for that category of laboratory, is provided continuously; and
- if pathology work is performed outside normal working hours and not in the presence of a supervisor as prescribed for that category of laboratory, then the work must be performed by staff who, because of their training and experience, are appropriate staff for the work (principle 9(2), Health Insurance (Accredited Pathology Laboratories—Approval Principles 1999).

### **Discussion Questions**

- 6.5 For pathology services accredited under the Commonwealth and Victorian schemes, does the Victorian requirement for 'direct supervision' of staff performing tests impose an additional burden?
- 6.6 Are you aware of any evidence to suggest that the Victorian requirement for 'direct supervision' achieves a superior outcome to the performance of similar pathology services in other State/Territories?
- 6.7 In your view, how reasonable is the Victorian requirement for the 'direct supervision' of staff?
- 6.8 Where pathology tests are conducted outside of normal working hours by appropriately experienced and qualified staff, would the availability of an appropriately qualified pathologist who would be able to answer telephone queries and view images transmitted over the Internet constitute adequate supervision?

#### **6.2.4 Prosecutions**

Powers exist under the Act for prosecutions to be launched in relation to both fraud and the performance of unaccredited testing. No prosecutions have been undertaken in the ten years during which accreditation has operated. A small number of complaints have been received regarding the conduct of screening tests by unaccredited providers, particularly the provision of cholesterol testing in shopping centres. In these cases, the PSAB has sought to work co-operatively with local government to close such operations, rather than commencing prosecutions.

The Review Panel has noted that regulatory boards are frequently reluctant to launch prosecutions where poor practice is identified. It is understood that the costs of mounting prosecutions are high and regulatory boards are generally poorly resourced. However, in terms of the PSAB, the Review Panel is not aware of any significant evidence to suggest that complaints liable to lead to prosecution have been forthcoming<sup>16</sup>. As noted above, the PSAB's investigative activity has also been limited. In summary, the Review Panel has formed the view that prosecution activity has not been an important mechanism by which the performance of the pathology services industry has been assured.

#### **6.2.5 Suspension/Cancellation/Non-Renewal of Accreditation**

There has been a total of four cases of cancellation or non-renewal of accreditation over the past ten years. Three of these cases related to the non-completion of accreditation requirements, while the fourth related to non-compliance with a direction from the PSAB. It was not clear to the Review Panel whether this fourth case also involved an inquiry by the PSAB.

#### **6.2.6 Assessment Reports**

In addition to being a requirement for initial accreditation, assessment of a pathology service may also be required by the PSAB at its discretion. The PSAB has advised that almost all assessment reports identify at least some matters requiring remedial action.

<sup>16</sup> This view has been formed on the basis of information obtained from the PSAB in relation to the nature of complaints received.

Where the assessment reports indicate that the problems identified are substantial, the PSAB writes to the service provider urging that action be taken. Where these problems are particularly serious, the PSAB will issue a direction requiring that specific remedial actions be undertaken by a certain date.

Data are not available on the frequency with which such inspections by assessors are required by the PSAB, nor on the frequency with which the PSAB has written to, or formally directed, pathology services. Thus, a conclusion as to the likely impact of this mechanism in practice cannot be drawn with any confidence.

### **Discussion Questions**

- 6.9 Do you believe that the PSAB adds value to the NATA/RACGP assessment process by identifying matters requiring remedial action? Are you able to give any examples of the types of issues that have been identified as requiring attention?
- 6.10 Where matters of a more substantial nature have been identified as requiring attention, and the PSAB writes to the pathology services urging that action be taken, are follow-up assessments conducted? What mechanisms are in place to assist a pathology service in determining that an identified problem/issue has been adequately rectified?

### **6.2.7 Conclusion**

The above data suggest that the State's accreditation system has, on the whole, had little additional impact in preventing potential pathology service providers of inadequate quality from operating. No applications for accreditation have been rejected by the PSAB in the last ten years, while only four accreditations have been cancelled or refused renewal. This seems to indicate that the accreditation system has had limited impact in preventing sub-standard practitioners from operating. However, such a conclusion must be tentative, since the possibility exists that the existence and transparency of the accreditation requirements may have dissuaded some potential entrants to the industry prior to the formal application stage.

In relation to the impact of the accreditation system on standards of practice, the picture is somewhat mixed. On the one hand, the incidence of complaints, formal investigations and prosecutions is minimal. On the other hand, numerous instances have been documented in which written requests or directions from the PSAB have followed negative inspection reports and problems with practice standards have been seen to be resolved.

In summary, the Review Panel has noted that the PSAB has generally chosen to conduct its tasks using relatively informal instruments and, hence, there is necessarily some lack of transparency in its operations that makes judgements as to the extent of its impact on practice in the industry unclear.

### **Discussion Questions**

- 6.11 Do you believe that the accreditation system has had clearly identifiable impacts on pathology practice in Victoria?
- 6.12 If so, what are the key benefits that have been associated with the accreditation system?
- 6.13 What are the major costs associated with the accreditation system?
- 6.14 Do you believe that the accreditation system achieves benefits in relation to pathology services that are also accredited by the Commonwealth Government? If so, what is the source of these additional benefits?
- 6.15 What are the major benefits (if any) of the Victorian accreditation system in relation to pathology services that are not accredited by the Commonwealth Government?

## **6.3 Meeting the Public Benefit Test—Benefits Versus Costs**

The preceding sections have discussed possible indicators of the benefits delivered by the accreditation process. However, the public benefit test applied under the NCP requires it to be established that there are net benefits associated with the restrictions on competition. It is therefore necessary to consider the costs of the accreditation system. These can be considered in two parts:

- the costs imposed on pathology services that are also accredited under the Commonwealth scheme; and
- the costs imposed on services that would not otherwise be accredited.

### **6.3.1 Pathology Services Subject to Dual Accreditation**

The Commonwealth's accreditation system is substantively identical to that operating in Victoria. Differences have arisen over time in relation to the application forms used and in relation to the registration categories, although the recently adopted Victorian regulations act, in part, to address some of these inconsistencies. A further difference lies in the nature of the approvals bodies.

In both cases, the approval process is based on an assessment report from the National Association of Testing Authorities (NATA) (or in the case of Category M pathology services, the RACGP). At the Commonwealth level, the decision to accredit a pathology service is made by officers of the HIC—informed by the inspection report. By contrast, the accreditation decision in Victoria is made by an industry-based committee which also has a community representative nominated by the Minister for Health. In both cases appeal mechanisms exist. Under the Victorian legislation, appeals are to the County Court.

Given that the accreditation requirements of the Commonwealth and Victorian schemes are largely identical—as a matter of conscious policy—the costs to nationally accredited pathology services of obtaining accreditation under the Victorian system are small. In essence, these costs are likely to be limited to the paper work burden involved in completing and sending application forms and answering any queries from the PSAB, plus the requisite fees. The recently published Regulatory Impact Statement (RIS) relating to the new Victorian pathology services regulations estimated the paper burden costs of

accreditation at around \$160.00 per pathology service, or a total of about \$22,000.00 *per annum* for the 137 Victorian pathology services accredited by the Commonwealth. Section 6.3.3 below will discuss the accreditation fees paid by pathology services.

### **6.3.2 Pathology Services Not Accredited by the Commonwealth**

The remaining group of pathology services numbers approximately 42 (that is, the difference between the number of Victorian accredited services and the number of Commonwealth accredited services operating in Victoria). The Review Panel believes that this group may comprise the following types of services:

- Services which only perform testing for screening purposes, including State and Commonwealth Government funded screening services and community health centres;
- Research laboratories;
- Private laboratories which perform specialised testing for which Medicare rebates are not paid; and
- Reference laboratories.

For pathology services in this group, the major costs imposed by the accreditation system appear to be the following:

- Paper work burden of applications for registration, together with answering queries from the PSAB;
- Incremental staff costs to comply with minimum qualification requirements for staff (these may be significant for services, such as Commonwealth or State funded screening services, that conduct a narrow range of tests and may otherwise have chosen to use less highly qualified technicians);
- Implementation of a quality management system, including quality management manual requirements;
- Costs of assessment as required prior to accreditation being granted; and
- Fees payable to the PSAB (see below).

The RIS estimated the likely costs for accreditation paper burden and quality management system documentation would include one-off costs of around \$278,000.00 and annual costs of approximately \$184,000.00. No estimates were made of incremental staff costs, which would essentially relate to the employment of more highly qualified supervisors than might otherwise be chosen in some cases. Similarly, no estimates of the costs associated with pre-accreditation assessments were included. These costs contain two major elements. The first are those costs borne by pathology services in preparing for assessments, providing assistance to assessors, and the like. The second group of costs is those incurred by the assessment team and by NATA. As assessors are drawn from the pathology industry itself, these costs are internal to the industry, but are not fully recovered from the pathology service seeking accreditation. Involvement in the process as an assessor is on a voluntary basis, so these costs are voluntarily borne.

### **6.3.3 Costs of the PSAB**

A third element of the costs of the accreditation system comprises the costs directly associated with the PSAB. The major visible costs of the PSAB are the costs associated with the provision of a Registrar. These costs are estimated at approximately \$72,000 per annum, inclusive of overheads. Other costs include the sitting fees paid to PSAB members (it is understood that not all members accept sitting fees) and the ancillary costs of postage, printing and the like. In the event that any prosecutions were undertaken, or investigations requiring the use of external resources, substantial additional costs could be

generated. However, as noted above, these have rarely been incurred during the life of the PSAB to date.

A considerable proportion of these costs is ultimately borne by the pathology services, via the collection of annual accreditation fees. These fees are currently as follows:

- Categories G and B pathology services: \$410.00
- Categories M, S and U pathology services: \$176.00.

Total fee revenue is estimated at approximately \$60,000.00. It is apparent that the fees revenue does not fully recover the costs to the Victorian Government of the accreditation scheme. The remainder of these costs is met by direct and indirect subsidies from the budget of the Department of Human Services.

It is generally expected that industries should pay the costs of their regulation, and most fees of equivalent type to the pathology accreditation fees are, accordingly, calculated to recover these regulatory costs. The fact that the existing fees depart from this presumption may be due in part to the relatively small costs and revenues involved and past lack of rigour in fee determination. It may also reflect a desire to ensure that fees are not seen to be excessive in a context in which additional fees will be paid by most pathology services for equivalent Commonwealth accreditation. Notwithstanding the latter factor, it is certainly arguable that the accreditation fees should recover the costs of the PSAB's operations.

#### **Discussion Questions**

- 6.16 Does the above discussion identify the full range of costs attributable to the Victorian system of accreditation of pathology services? If not, what additional cost items should be considered?
- 6.17 Can you provide additional data or estimates to assist in the quantification of any of the above cost items? Are you aware of any other potential sources of data on this issue?
- 6.18 Are there means of reducing the costs associated with the accreditation system while retaining its key benefits?
- 6.19 Can the accreditation system be made more effective and efficient?

It is often difficult to quantify costs and benefits, particularly where benefits are subjective or otherwise difficult to express in dollar terms. However, it should be possible to:

- describe the intended benefits to the whole community; and,
- furnish evidence that the regulation contributes to the desired outcome (that, is achievement of the legislation's objectives).

In demonstrating that legislated restrictions on competition or other aspects of industry practice via legislation are the only way to achieve the objectives sought, it must also be shown that other means of achieving the objectives of the legislation are less effective and efficient. The discussion that follows will consider the current legislation and alternative measures that could be used to achieve the objectives of the legislation.

# 7. Alternatives to Statutory-Based Accreditation

A series of alternatives to the current Victorian pathology services legislation, which could foster the maintenance of high standards within the pathology industry, are presented in the discussion that follows. When considering the extent to which each existing mechanism operates to assist in ensuring industry standards are met and maintained, consideration should also be given as to whether a combination of these mechanisms could provide an appropriate alternative to the current regulatory regime.

## 7.1 Non-Regulatory Mechanisms

### 7.1.1 Role of Health Service Providers

As discussed earlier, in the majority of cases, consumers of health services (patients) do not directly use pathology services. A health care practitioner, usually a medical practitioner, determines which pathology tests are required, orders the tests and subsequently interprets the results. The health care practitioner thereby functions as an intermediary between the patient and the pathology service provider. Further, it is plausible that, because of the health care practitioner's knowledge and experience, the consumer may either defer the decision about choice of pathology service provider to the health care practitioner or be guided in making that choice by the health care practitioner. This action is significant in that where a pathology service conducts tests for the health care provider, that health care provider is in a better position than the patient to identify poor pathology practice over a period of time and thus is better equipped to take some form of action.

#### Discussion Questions

- 7.1 As registered medical practitioners are entitled to order any test from any pathology provider accredited to supply them, what influences choice of service provider?
- 7.2 How, if at all, do market forces act to influence this choice?
- 7.3 Is the Review Panel's assumption that consumers defer, to the health care provider, the issue of choice of pathology service provider a valid assumption?

### 7.1.2 Common Law

There is a body of law that has an impact upon the standards of practice and conduct of service providers. The body of law known as civil liability at common law has traditionally involved the courts resolving certain kinds of disputes between individuals, where those individuals are unable to settle their disagreements privately.

Where a dispute involves a person alleging that he or she has suffered injury or illness as a result of receiving some kind of health service, the legal action that is usually pursued is the civil tort of negligence. There are a number of elements that a court must be satisfied about, if it to find in favour of a consumer (the plaintiff), and to find against the health care provider or the pathology service provider (the defendant). Each party may call evidence and present arguments to persuade the court about the following:

- whether the defendant owes the plaintiff a 'duty of care';
- whether the provider breached the appropriate standard of care; and,
- whether that breach caused or exacerbated the injuries or illness of the plaintiff.

In addressing these three elements of negligence a court focuses on the conduct of the individual litigants before it and makes a finding that can determine how loss is to be distributed between the defendant and the plaintiff. The decision that a court makes in a particular case may well have ramifications for the wider industry. One of the benefits of a court's decision may be improvement in health care providers' or pathology providers' practice. If a provider is found to be negligent in a particular instance, his or her colleagues will be interested in the court's finding, and may choose to modify their behaviour if they believe that they are otherwise at risk of being sued by their own patients.

### **Discussion Questions**

- 7.4 Is the availability of the common law for redress of complaints an adequate alternative to legislation, or is there a need to provide additional safeguards for the public?
- 7.5 Has the availability of common law actions assisted in ensuring that pathology services industry standards are maintained? How?
- 7.6 Could any actions be taken that would render the common law more effective as an alternative?

## **7.2 Office of the Health Services Commissioner**

An alternative to court-based litigation for the redress of complaints about the provision of health services is the Office of the Health Services Commissioner. Since commencing its statutory functions in 1988, the Office of the Health Services Commissioner has provided an accessible, inexpensive, timely and independent mechanism for the resolution of disputes between health service providers and patients. While the current *Health Services (Conciliation and Review) Act 1988* does not expressly include pathology services in its definition of health services, the purview of the Office of the Health Services Commissioner does, in fact, extend to these services (Health Services Commissioner, 1999). Section 3 of the Health Services (Conciliation and Review) Act includes hospital and medical services and services provided by practitioners in alternative health care fields amongst the list of health services to which the Act applies. While legislation governing dispute resolution does not directly inform standards maintenance, indirectly its operation makes providers aware that a 'watchdog' exists.

### **Discussion Questions**

- 7.7 Has the availability of a formal complaints mechanism assisted in ensuring that pathology services industry standards are maintained? How?
- 7.8 Is the availability of the Office of the Health Services Commissioner for redress of complaints an adequate alternative to legislation, or is there a need to provide additional safeguards for the public?
- 7.9 What more could be done to render the Office of the Health Services Commissioner an adequate alternative?

### 7.3 Fair Trading Act 1999

The *Fair Trading Act 1999* (Vic) provides for a process of resolving consumer disputes, which can involve conciliation and/or hearing. In limited circumstances, and where there is an issue of public interest at stake, the Director may, with the consent of the Minister and the relevant party, institute or defend proceedings on behalf of one of the parties.

Although the definitions of ‘consumer dispute’ and ‘service’, within the Fair Trading Act do not specifically refer to complaints about health services, the Act could be applied to complaints about provision of health services. It appears, however, that the broad powers in relation to investigating complaints made under the Fair Trading Act have rarely been used in relation to health services complaints. This may be because of a community-held perception that health services complaints do not fit within the fair trading jurisdiction. It may also be that the Health Services Commissioner is regarded as having the necessary and particular expertise in the area of dispute resolution of health service matters.

In addition, a party to a dispute can institute proceedings for a breach of the Fair Trading Act in the Victorian Civil and Administrative Tribunal. The Tribunal can make any order it thinks fit, including an order for damages. Complaints that are determined at hearing are enforceable at law, ensuring a finality of outcome for the user.

#### Discussion Questions

- 7.10 Has the availability of consumer protection laws, such as the Fair Trading Act assisted in ensuring that pathology services industry standards are maintained? How?
- 7.11 Is the availability of consumer protection laws an adequate alternative or is there a need to provide additional safeguards for the public? What more could be done to render consumer protection laws a more feasible alternative?

### 7.4 Other Mechanisms

As indicated earlier, irrespective of their accreditation status with the Commonwealth, for many pathology services accredited under Victorian law there are a number of non-statutory based ‘accreditation’ or ‘quality assurance’ mechanisms which are imposed by industry or voluntarily undertaken as part of a self-regulation process. Further, financing or contractual obligations or insurance requirements might also require pathology services to be NATA accredited.

Other controls, which may impact upon the maintenance of quality standards and conduct of pathology services, include:

- restrictions on the use of equipment under the Therapeutic Goods legislation (Commonwealth and Victorian); and
- public health measures such as infection control requirements under the *Health Act 1958* (Vic).

### **Discussion Questions**

- 7.12 Has the availability and use of non-statutory based accreditation or quality assurance mechanisms assisted in the maintenance of quality standards? How?
- 7.13 Could these mechanisms, with or without Commonwealth accreditation requirements for Medicare reimbursement purposes, act as an adequate alternative to State regulation or is there a need to provide additional safeguards for the public?
- 7.14 Could a combination of alternative mechanisms replace the current statutory framework and still maintain adequate safeguard for the public? What combination of alternative mechanisms would be ideal?

## **7.5 Applying the Alternatives**

To ascertain whether contractual and industry-based practices plus dispute resolution mechanisms afford adequate safeguards for the public against the risks posed by the provision of pathology services, it would be useful to consider pathology services according to their eligibility to seek Medicare rebates from the Commonwealth.

Consequently, the following discussion will be separated into two parts:

- (a) pathology services seeking Medicare rebates; and
- (b) pathology services that are ineligible to seek or do not seek Medicare rebates.

### **7.5.1 Pathology Services Eligible to Seek Medicare Rebates**

This group of pathology services falls under the legislative purview of both the Commonwealth and Victoria. Essentially, the services in this group provide mainstream pathology services (such as Full Blood Examinations or PAP smear analyses) in well-equipped, modern laboratories. As general practitioners increasingly refer patients to collection centres for specimen to be collected by staff of the pathology service, it is this group which consumers are the most familiar and associate with pathology testing (Deeble and Lewis-Hughes, 1991). While it is recognised that there are a number of specialised, single owner laboratories in this group, the majority of services belong to large corporations that operate pathology services both in Victoria and in other States and Territories.

Accordingly, the principal issues for this group are whether the requirement to be accredited in Victoria imposes a barrier to market entry and, whether the cost of accreditation under Victorian legislation imposes an unnecessary burden.

Amongst this group of pathology services are those for which Medicare remuneration applies only to a single test or to a small number of tests that are undertaken. For these services, dual Commonwealth and State accreditation may be disproportionate to the amount pathology testing conducted. Equally, accreditation under Victorian law may be imposing an additional burden in situations where 'accreditation' with other organisations such as the Therapeutic Goods Association, the American Society of Histocompatibility and Immunogenetics, the Australian & South East Asian Tissue Typing Association and the International Standards Organisation, occurs either voluntarily or as a mandatory requirement for business purposes such as obtaining medical insurance or contracts with corporations or government for service provision.

### **7.5.2 Pathology Services Ineligible to Seek or That Do Not Seek Medicare Rebates**

Only in Victoria does this group of services fall under any legislative purview relating to pathology service provision. Victorian law prohibits the conduct of any diagnostic service that may be deemed a 'pathology service' without that service being conferred deemed accreditation or accreditation status under the Pathology Services Accreditation Act. The PSAB (1994) has advised that the types of services which would fall into this category include research and reference laboratories, alternative health care services, the Red Cross Blood service and providers of screening tests such as cholesterol and drug screening.

As with services grouped in part 7.5.1, the principal issues for this second group are whether Victorian law imposes a barrier to market entry and whether accreditation is not only necessary to protect the public but whether the costs of accreditation are commensurate with any derived benefits. Consideration should therefore be given to whether accreditation under Victorian law is necessary to protect the public, given that no other State or Territory imposes the same requirements as Victoria on the conduct of such services.

Other concerns for services grouped in this part include whether:

- the definition of pathology services has been interpreted too broadly and perhaps has inappropriately captured services whose work is not concerned with the analysis of specimen for the purposes of prevention, diagnosis or treatment of disease; and
- accreditation costs are in proportion with the amount of pathology testing undertaken.

As with some of the services in part 7.5.1, accreditation under Victorian legislation may be imposing an additional burden in situations where 'accreditation' with other organisations such as the Therapeutic Goods Administration, the American Society of Histocompatibility and Immunogenetics, the Australian & South East Asian Tissue Typing Association and the International Standards Organisation, occurs either voluntarily or as a mandatory requirement for obtaining medical insurance or contracting with corporations or government for service provision.

#### **Discussion Questions**

7.15 In other States and Territories, does the availability of other 'accreditation' mechanisms (such as those listed above) and/or the commercial impetus to be 'accredited' (perhaps as a requirement for insurance) provide reasonable safeguards for the public?

Given the varied nature of the services that comprise this group, it would be useful to consider a series of questions in terms of each type of service.

## **Research Institutes and Reference Laboratories**

### **Discussion Questions**

- 7.16 Does the work undertaken by research institutes directly inform the health care of an individual?
- 7.17 Should the accreditation scheme apply to such facilities?
- 7.18 Are the various mechanisms for peer review of work undertaken in scientific research adequate to ensure that work meets best practice in terms of technique and reporting?
- 7.19 Could conditions be incorporated into State and/or Commonwealth funding agreements to ensure that these services are subjected to 'accreditation' processes such as the ISO program?

## **Screening Services and Alternative Health Care Providers**

### **Discussion Questions**

- 7.20 How appropriate is it to capture these services under pathology services legislation?
- 7.21 What are the potential risks to the public in the provision of these services?
- 7.22 Are there alternative and less restrictive methods of protecting the public than statutory regulation?
- 7.23 Would the public be exposed to an unacceptably high level of risk if a less restrictive form of regulation were adopted?

## 8. Options

Set out below are five options for reform of the current arrangements governing the regulation of the pathology services industry in Victoria. These options have been raised for the purposes of discussion only. These options are not listed in any particular order and their ranking should not be construed as a reflection of the policy preferences of the Review Panel. Further, no one option should be construed as representing the final position of the Review Panel. At this stage, the Review Panel will not recommend any one option as the most appropriate as it will reserve its decision pending consideration of submissions from interested individuals and the pathology services industry. To this end, the Review Panel would welcome the submission of any alternative options for its consideration.

### **Option 1: Retain statutory accreditation system in Victoria but make it consistent with the model framework for the regulation of health service practitioners**

This option entails retaining Victoria's current statutory system of accreditation of pathology services in its present form, but amending the Pathology Services Accreditation Act to reflect the key elements of the model framework that applies to the regulation of health practitioners<sup>17</sup>. This would involve amending the Act to ensure that:

- its stated objective is to protect the public by ensuring appropriate standards of practice in pathology services;
- the PSAB is to be incorporated separately and responsible for hiring its own staff and managing its own affairs;
- PSAB membership is not reserved by statute for nominees of particular organisations;
- PSAB membership includes at least one person able to bring a consumer perspective to its deliberations and a lawyer (given that it performs legal functions in making decisions about accreditation);
- appeals against board decisions lie to the Victorian Civil and Administrative Tribunal (VCAT); and
- the power to make regulations is vested in the Governor in Council.

Option 1 would be the most appropriate response if it were considered that:

- the potential for harm to patients inherent in the conduct of pathology services is such that specific State regulation is necessary to protect the public;
- the absence of State legislation would substantially increase the risk of harm to patients;
- other mechanisms such as Commonwealth accreditation, common law, State and Commonwealth consumer protection laws, market forces, contractual conditions imposed by payers, industry standards and insurance industry requirements which contribute to the maintenance of quality standards in the pathology industry are insufficient to protect the public, having regard to the potential for harm to occur as a consequence of the practice of pathology;
- the current legislation is a cost effective means of achieving the objective of protecting the public;

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<sup>17</sup> The former Health Department of Victoria conducted a review of health practitioner legislation resulting in a report by Carter and Loff entitled *Review of Registration for Health Practitioners*. The central recommendation of the report was a standardised approach to the regulation of health occupations by applying a consistent model.

- the benefits to the community of retaining the legislation, or, at least, retaining a legislative framework, outweigh the costs inherent in restricting competition; and
- in relation to pathology services which are subject to dual Victorian and Commonwealth accreditation legislation, that the Victorian accreditation system ‘adds value’ by affording patients and users of pathology services a greater level of protection than that afforded solely by the operation of the Commonwealth system.

## **Option 2: Retention of a statutory accreditation system with a simplified system of regulation**

Option 2 will incorporate option 1, which is, retaining Victoria’s current statutory system of accreditation of pathology services, but amending the Pathology Services Accreditation Act to reflect the key elements of the model framework that applies to the regulation of health practitioners. In addition to option 1, option 2 seeks to simplify the existing system of State regulation.

The 1995 *Review of Pathology Services Accreditation in Victoria*, reported that duplication arises between the Commonwealth and the State with regard to the administrative process of application for and assessment of accreditation. “Design of application forms, fees payable and the procedures of the contracted inspection bodies contain elements of duplication and unnecessary complexity, especially for applicants” (Department of Health and Community Services, 1995:iii).

Option 2 proposes to simplify the existing system of State regulation by establishing the Victorian accreditation authority as an agent of the Commonwealth in this State. With one jurisdiction governing pathology accreditation for all pathology services—irrespective of their Medicare eligibility—standing concerns to reduce duplication between the Commonwealth and Victoria would be addressed. These concerns were raised in the 1995 Review with the resultant recommendation that:

*...the Victorian Pathology Services Accreditation Board negotiate with the relevant Commonwealth officers to minimise differences in process and to reduce duplication for providers. Issues covered should include:*

- *reduction of Commonwealth fee charged to Victorian pathology services such that the combined Commonwealth/State fee is no higher than the single fee in other States*
- *single categorisation system*
- *design of a single application form suitable for either jurisdiction*

If this option was to be pursued, negotiations with the Commonwealth would have to be undertaken.

This option would be an appropriate response if it were considered that:

- the current accreditation process constitutes, in general terms, the most appropriate and effective means of ensuring high quality practice in the pathology services industry; and
- the key fault of the existing arrangement is the duplication which it imposes on pathology services that are currently required to be accredited under both Commonwealth and Victorian schemes.

### **Option 3: Residual 'safety net' system of regulation**

This option would entail Victoria retaining a residual 'safety net' regulatory system under which State legislation requiring accreditation would capture only those pathology services that are ineligible to seek accreditation under Commonwealth legislation for Medicare purposes or, are eligible to seek Commonwealth accreditation but choose not to do so. In establishing such a system, Victoria would continue to impose a barrier market entry for a range of services that, in other States and Territories, are not captured under a statutory accreditation scheme. The types of services that would fall under this residual system would include research and reference laboratories and alternative health care services and providers of screening tests such as cholesterol and drug screening.

This option would be the appropriate response if it was considered that:

- there is a very real and direct risk of harm to the public associated with the operation of such services which warrants the imposition of a regulatory system;
- the current accreditation process constitutes, in general terms, the most appropriate and effective means of ensuring high quality practice in the pathology services industry; and
- the key fault of the existing arrangement is the duplication which it imposes on pathology services that are currently required to be accredited under both Commonwealth and Victorian schemes.

The advantage of this option is that the majority of pathology services would no longer be subject to dual statutory accreditation requirements and the requirement to pay both Commonwealth and Victorian application fees. While Commonwealth accreditation would continue to apply to services that are eligible and seek Medicare rebates, the cost of regulation for these services would be reduced. Those services which are Medicare ineligible or are eligible but do not seek accreditation with the Commonwealth for Medicare purposes would continue to be regulated at the State level, thereby providing a certain level of assurance to users of such services.

A substantial disadvantage associated with this option is the cost involved in maintaining the infrastructure necessary to carry out the State regulatory function for a small number of pathology services. Government policy has required health practitioner registration boards to be self-funding. If a similar policy were to be applied to the regulation of pathology services, rendering a residual State safety net scheme viable would require State accreditation fees for pathology providers to rise substantially.

Information provided by the PSAB indicates that it currently accredits 42 more services than the Commonwealth scheme. While there are differences in the number of services included in Categories G, B, and M—compared with similar Commonwealth accreditation categories, the number of services eligible for capture under a residual scheme may even be fewer than 42 services.

There are currently 7 services in Category U and there are 21 more services accredited by the PSAB under Category S than accredited by the Commonwealth under the same category. Further, it may be successfully argued that the current Victorian definition of pathology services has been interpreted too broadly and thus may have inappropriately captured services whose work is not concerned with the analysis of specimen for the purposes of prevention, diagnosis or treatment of disease. In view of these numbers, accreditation fees for services captured under a residual system could be in the order of \$2,500–\$3,000 per annum.

Even if State fees were to be made consistent with the fees charged by the Commonwealth, it is likely that a significant State subsidy would be required in order to render such a scheme viable. Any increase in accreditation fees would be likely to be passed on to users of these pathology services unless prevailing market conditions were sufficiently competitive to prevent this from occurring. In these circumstances, the costs to providers and to Government of maintaining a system of regulation for those pathology services, which are not subject to Commonwealth accreditation requirements, are likely to outweigh the benefits to the public.

#### **Option 4: Negative licensing**

As indicated above, the Pathology Services Accreditation Act requires pathology services to be accredited so that the pathology business can be lawfully conducted in Victoria. The Act also regulates the qualifications of persons who can carry out certain functions within a pathology service.

Accreditation under the Pathology Services Accreditation Act may be regarded as a form of business licensing. Licensing schemes are premised on the need to pre-qualify participants seeking to engage in a defined field of activity, such as the carrying on of a pathology service. They thereby establish a form of barrier to entry in the defined field of business or activity and subject both exemplary performers and less ideal service providers to the same regulatory requirements and the costs associated with regulation.

Negative licensing is a fairly novel approach to regulation. It differs from traditional licensing schemes in that it does not involve establishing an initial statutory requirement to be assessed and approved by a regulatory authority in order to be able to lawfully carry on a business or engage in a defined field of activity. According to the Commonwealth Office of Regulation Review, "...negative licensing occurs where agents are not screened before starting to practice, but are only prohibited from practising if shortcomings in their practice are identified subsequently" (1994:36).

The Review Panel has been unable to find any examples of a pure negative licensing scheme in which there is no requirement for the statutory approval of a service provider and/or service in order to lawfully commence operation of that service. However, there are examples of schemes with minimal professional entry requirements, but where the on-going right to practice depends on continuing compliance with statutory requirements. Two examples of schemes regarded as negative licensing are the regulation of credit providers and the regulation of estate agents (see Box 8.1).

Negative licensing would involve the enactment of legislation to provide a mechanism whereby a competent authority such as a Government department, a statutory authority or a tribunal can effectively disqualify a person who has proven to be unfit to engage in a field of activity or to carry on a business from doing so in the future, or can impose conditions on the conduct of a pathology service in order to protect the public. In effect, it provides a means of removing the legal right to participate in an industry from those who have proven by their conduct to be unfit to participate in that particular industry or requires those whose practice has been sub-optimal to submit to certain controls on their conduct.

Although the concept of negative licensing has received some attention recently, this form of regulation has few known statutory precedents in Victoria. Therefore, if this option were to be pursued, careful consideration would need to be given to a range of policy, drafting and implementation issues including:

- the types of activities or behaviour which would trigger an inquiry into whether or not a person is fit and proper to engage in the provision of pathology services;
- who should be empowered to gather evidence and initiate such an inquiry;
- the type of body which should be empowered to inquire into and make determinations on fitness to conduct a pathology service (for instance, should the competent body be a Government Department, an independent statutory body such as the Business Licensing Authority or the Office of the Health Services Commissioner or, a specialist statutory body, tribunal or court?);
- the jurisdiction and powers of such a body;
- the grounds for removal of the legal right to provide or be involved in the provision of pathology services; and,
- appeal rights against determinations.

### **Box 8.1: Examples of Negative Licensing Schemes**

#### **Example 1a: *Credit Administration Amendment Act 1993 (Vic)***

Subject to meeting certain conditions outlined in the Act, credit providers are automatically registered. However, the Act requires that, where necessary, a credit provider can be required to give an undertaking:

- to refrain from specified conduct; or
- to engage in specific conduct; or
- to take specified action to rectify the consequences of past conduct.

Failure to comply with the requirements of the Act can lead to cancellation of registration.

#### **Example 1b: *ACT Consumer Credit (Administration) Act 1996***

The ACT Consumer Credit (Administration) Act appears to be based upon the Victorian Credit Administration Amendment Act (Example 1a above).

The Act introduces a scheme of negative licensing with registration of credit providers and finance brokers by setting minimal barriers to entry. If the applicant meets the criteria in the application process, the Director of Consumer Affairs is obliged to register the applicant. Once registered, the applicant is only obliged to submit an annual fee to maintain registration. However, there is a range of disciplinary powers available to the Director including suspension of registration.

#### **Example 2: *Estate Agents (Amendment) Act 1994 (Vic)***

Until recently, Victoria had a two-tiered licensing system for real-estate agents. This required agents and sub-agents to obtain a personal licence. Sub-agent licensing required that a person be assessed by an independent regulatory body as meeting eligibility criteria before being granted a licence. The eligibility criteria included requirements concerning age, qualifications and criminal history.

The Estate Agents (Amendment) Act abolished sub-agents licences and reclassified sub-agents as agents' representatives. It transferred the statutory responsibility for assessing a person's eligibility for employment as an agents' representative to the estate agent and it implemented a negative licensing system for agents' representatives.

The negative licensing system allows the Estate Agents Licensing Authority to apply to the Estate Agents Disciplinary and Licensing Appeals Tribunal to determine whether an agent's representative:

- is eligible;
- is of good character or is otherwise a fit and proper person to be an agents' representative;
- has been guilty of conduct as an agents' representative which renders him/her unfit to be an agents' representative; or
- has contravened or failed to comply with the Act.

The Estate Agents Licensing Authority is also responsible for maintaining a record of the details of people employed as agents' representatives and a register of persons ineligible to be employed in the real estate industry.

Negative licensing has the potential to be a cost effective means of protecting the public by ensuring that action can be taken to remove, from the industry, any persons who have proven by their behaviour to be unfit to conduct or be involved in the conduct of pathology services. This is achieved without imposing the additional burden of State regulation on the majority of pathology providers, most of which are captured under the Commonwealth scheme. Negative licensing may be the appropriate regulatory solution if:

- the risk associated with unregulated pathology services is considered to not be so high as to require State based legislation regulating the entire industry or those providers who are not captured under the Commonwealth scheme; and
- there is sufficient community concern about the risks to warrant some form of contingency measure in the event that a substantial risk to public health associated with the practices of any particular pathology service does subsequently emerge.

### **Option 5: Repeal of the *Pathology Services Accreditation Act***

This option would involve repealing the Act and relying on a combination of Commonwealth accreditation and other non-regulatory mechanisms such as common law, industry self-regulation, contractual arrangements with payers and so on to assist in ensuring that appropriate standards are maintained within the industry in Victoria.

The implementation of this option would bring Victoria into line with other States which have not perceived the risks associated with pathology practice to be such as to warrant the enactment of State based legislation to supplement the Commonwealth regime of controls and existing non-regulatory mechanisms. It would also facilitate competition by removing a barrier to entry into the pathology services market in Victoria and would thereby reduce costs to industry and Government, as the current regulatory system is subsidised.

This option would be appropriate if it was considered that:

- the risks associated with pathology services in Victoria were similar to those in other States and Territories;
- the existing standard of practice in other States and Territories, which do not currently have separate accreditation schemes, is generally acceptable;
- there is little concrete evidence that the current accreditation regime has provided substantive benefits to consumers of pathology services; and
- the alternative means of ensuring high levels of practice in pathology services outlined above were, as a result, considered to be adequate.



# Appendices

# Appendix A

## Terms of Reference—National Competition Policy Review

### ***Review of the Pathology Services Accreditation Act and Associated Regulations***

The review of the Pathology Services Accreditation Act and associated regulations has been commissioned by the Minister for Health in accordance with the Victorian Government *Timetable for the Review and Reform of Legislation that Restricts Competition*, determined in accordance with the National Competition Policy.

#### **Legislation to be Reviewed**

The Review Panel will examine the case for reform of legislative restrictions on competition contained in the Pathology Services Accreditation Act, the Pathology Services Accreditation (General) Regulations and Pathology Services (Exempted Tests) Regulations, in accordance with the Victorian Government's *Guidelines for the Review of Legislative Restrictions on Competition*.

In particular, the Review Panel will:

- clarify the objectives of the legislation;
- identify the nature of the restrictions on competition imposed by the legislation and regulations;
- analyse the likely effect of any identified restriction on competition and on the Victorian economy in general;
- assess and balance the costs and benefits of the restriction identified to the Victorian community; and,
- consider alternative means for achieving the same result, including non-legislative means.

The Review Panel will provide evidence and findings in its report in relation to these matters.

#### **Reform Options**

Without limiting the scope of the review, the Review Panel should specifically address the appropriateness of removing restrictions imposed upon the Victorian pathology services industry such as:

- advertising of pathology services;
- employment of staff and qualifications of the person in charge of a pathology service;
- minimum standards for matters including equipment, facilities, reporting and quality control; and
- performance of certain tests by pathology services while ensuring that consumers are adequately protected through the performance of safe and technically appropriate diagnostic practices.

#### **Review Arrangements**

This review is to be established and conducted in accordance with Model 2 (semi-public review) contained in the Guidelines.

# Appendix B

## Terms of Reference—1995 Review of Pathology Services Accreditation in Victoria

### Aim

In view of the fact that two schemes of pathology services accreditation exist in Australia—one for Victoria administered by the Pathology Services Accreditation Board (PSAB) and one for all States administered by the Commonwealth Department of Human Services and Health, the aim of the review is to clarify the state of pathology services accreditation and to determine the best possible accreditation system for Victoria.

### Objectives

With regard to appropriate levels of industry and Government consultation, the objectives of the review are to:

- Examine the functions and responsibilities of the PSAB and the process of accreditation in Victoria.
- Examine the functions and responsibilities of the relevant Commonwealth bodies associated with pathology services accreditation, and the process of accreditation in other States.
- Investigate and document any duplication or overlap of core functions and responsibilities across the Commonwealth and Victorian bodies related to pathology services accreditation, and in doing so highlight the difference between them.
- Investigate and document the feasibility and likely effects of abolishing the PSAB and transferring its functions and responsibilities to the Commonwealth or devising a new regulatory framework for pathology services in Victoria. This should focus on standards of pathology service accreditation and public health in Victoria as well as on the pathology industry generally and any other aspects the Working Party wishes to consider.
- Draw a conclusion which identifies the best possible pathology service accreditation system for Victoria.

### Outcomes

Prepare a report to the Minister for Health addressing the review's aims and objectives.

Make appropriate recommendations to the Minister for Health concerning pathology service accreditation arrangements in Victoria.

# Appendix C

## **Review of Pathology Services Accreditation in Victoria, 1995, Recommendations of the Working Party**

The recommendations of the Working Party were:

- (i) That the Victorian Pathology Services Accreditation Board be retained as the primary accrediting body in Victoria.
- (ii) That the Victorian Pathology Services Accreditation Board negotiate with the relevant Commonwealth officers to minimise differences in process and to reduce duplication for providers. Issues covered should include:
  - reduction of Commonwealth fee charged to Victorian pathology services such that the combined Commonwealth/State fee is no higher than the single fee in other States
  - single categorisation system
  - design of a single application form suitable for either jurisdiction

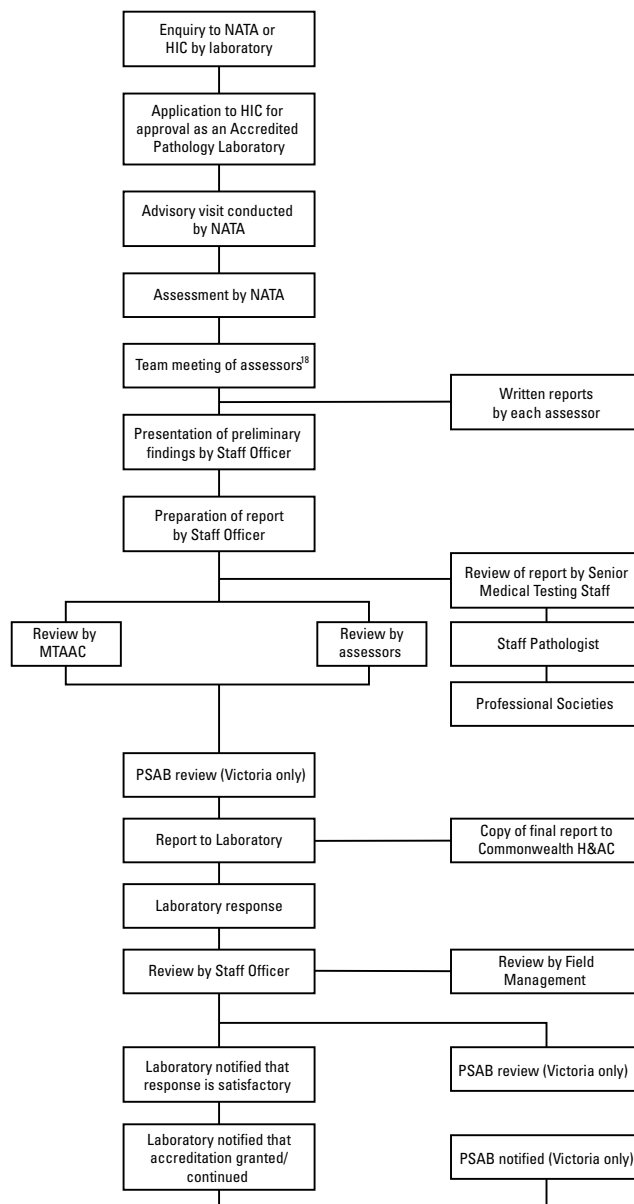
If negotiations are unsuccessful, it is recommended that the Minister for Health make representations to the Commonwealth Minister for Human Services and Health requesting the required changes.

- (iii) That a review of the Pathology Services Accreditation Act 1984 be undertaken immediately with particular reference to Part V which relates to proprietorship of pathology services in Victoria.
- (iv) That the Department of Health and Community Services analyse the potential effects of any changes in policy or funding mechanisms at the Commonwealth level which occur and advise the Minister for Health of any requirement for a further review of the accreditation system in Victoria.

# Appendix D

## The Commonwealth Accreditation Process

Upon application to the HIC, accreditation is granted initially on the basis of information submitted by the applicant. The status of this accreditation is reviewed annually. NATA, in association with the Royal College of Pathologists of Australasia conducts an assessment to determine technical competence and if the outcome is satisfactory, accreditation by NATA/RCPA is granted. Generally the HIC, in turn, extends its accreditation thus assuring the continued payment of Medicare benefits.



*Adapted by kind permission of NATA*

<sup>18</sup> The NATA accreditation process is predicated on peer review. Hence, assessors are appointed, on a volunteer basis, from the pathology industry. NATA undertakes a comprehensive matching process to ensure that the experience of each assessor is commensurate with the work undertaken by the laboratory being assessed. The PSAB, in turn, evaluates the suitability of the assessors appointed to inspect Victorian services.

# Appendix E

## Commonwealth *Health Insurance (Accredited Pathology Laboratories—Approval) Principles 1999—Accreditation Categories*

Category	Description
GX (General)	Premises comprising a laboratory, or a number of co-located laboratories, performing services in one or more groups of pathology: (a) under the direction, control and full-time supervision of a pathologist, or senior scientist, who is expert in the group or groups, concerned; and (b) at which the number of working pathologists (whether full-time or part-time) is equivalent to more than 2 full-time pathologists.
GY (General)	Premises comprising a laboratory, or a number of co-located laboratories, performing services in one or more groups of pathology: (a) under the direction, control and full-time supervision of a pathologist, or senior scientist, who is expert in the group or groups, concerned; and (b) at which the number of working pathologists (whether full-time or part-time) is equivalent to not more than 2 full-time pathologists.
B (Branch)	Premises comprising a laboratory performing services in one or more groups of pathology, being a laboratory related, by appropriate arrangement, to an accredited pathology laboratory of category GX or GY, as: (a) a branch, integral (except in its location) with the category GX or GY laboratory; or (b) a member of participating laboratories in a regional pathology services; operating under: (c) the direction and control of a pathologist, or senior scientist who is expert in the group, or groups, concerned; and (d) the supervision of at least a scientist, who is expert in the group, or groups, concerned.
M (Medical)	Premises comprising a laboratory performing pathology services under the direction, control and supervision of a medical practitioner, being services only for the patients of the medical practice operated by, or that employs, the medical practitioner.
S (Specialised)	Premises comprising a laboratory performing a limited range of pathology tests under the supervision of a person with special qualifications or skills in the field of those tests, that are tests: (a) performed for a 'particular target population' or are of a specialised nature; and (b) are performed in the field of those special qualifications or skills.

# Appendix F

## Victorian *Pathology Services Accreditation Act 1984*— Accreditation Categories

Former Categories	New Categories (as at 26 February 2001)
<p><b>Category 1</b> Services where tests in several divisions of pathology are performed and the person in charge is a pathologist.</p>	<p><b>Category G (General)</b> A pathology service consisting of one laboratory or a group of laboratories at the one location, where tests in one or more divisions of pathology are performed, and where there is direct, full-time or equivalent full-time professional and scientific accountability and supervision by a pathologist or pathologists or by a scientist or scientists.</p>
<p><b>Category 2</b> Services in which a range of tests predominantly within only one division of pathology is performed. Each such service shall be under the direct full-time supervision of a pathologist qualified in that division of pathology or of a scientist with prescribed qualifications and who has had, in the opinion of the Board, satisfactory and extensive experience in the work of that division of pathology.</p>	<p><b>Category B (Branch)</b> A pathology service in which the range of pathology tests provided and the standard of work is under the direction and control of a designated pathologist or scientist employed in an accredited Category G pathology service. The pathology service must have an on-site scientist providing day-to-day supervision and a written agreement with the Category G pathology service for direction and control as required for this Category and be either an integral part of the Category G laboratory, except for its location, or a part of a regional pathology service.</p>
<p><b>Category 3</b> Services in which the range of tests undertaken and the standard of the pathology service shall be under the direction and control of a pathologist from a Category 1 service, or a pathologist or scientist from a Category 2 service.</p>	
<p><b>Category 4</b> Services of “recognised hospitals” within the meaning of the Health Insurance Act 1973, other than services Category 1, 2, or 3. These services shall meet the requirements of a Category 1,2, or 3 service within two years after the commencement of section 14.</p>	

**Category 5**

Services in which pathology tests approved by the Board are performed by or under the supervision of a registered medical practitioner for patients of the medical practitioner or practitioners of whose practice the service is a part.

**Category 6**

Services in which is performed a limited range of pathology tests approved by the Board, where those tests are of a specialised nature and are performed under the supervision of a person having special qualifications or skills, acceptable to the Board, in the field of those tests.

**Category 7**

Services located in isolated areas in which pathology tests approved by the Board are performed.

**Category 8**

Services approved by the Board of a type which do not fall within any other Category.

**Category M (Medical Practitioner)**

A pathology service in which tests approved by the Board are performed by or under the supervision of a registered medical practitioner for patients only of the medical practice in which the practitioner works.

**Category S (Specialised)**

A pathology service in which is performed a limited range of pathology tests approved by the Board, where those tests are either conducted on a particular target population or are of a specialised nature and are performed under the supervision of a person having special qualifications or skills, acceptable to the Board, in the field of those tests.

**Category U (Unspecified)**

Services approved by the Board of a type which do not fall within any other Category.

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