

Review of the Victorian Pathology
Services Accreditation Act 1984

Final Report

This Final Report is also available on the Internet at: <http://www.dhs.vic.gov.au/ahs/legal.htm>

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14 February 2002

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

Dear Minister

I have pleasure in submitting the final report of the review of the *Pathology Services Accreditation Act 1984*.

With the release of a Discussion Paper in May 2001, the Review Panel sought the views of individuals and organisations with an interest in how pathology services are regulated. A number of submissions were received all of which offered valuable insights and views about the regulation of the provision of pathology services in this State. The submissions provided a substantial contribution to the Review Panel's deliberations and formulation of its recommendations.

The Review Panel believes that implementation of its recommendations will, when considered in conjunction with the existing mechanisms for ensuring quality service provision in the health system, support the maintenance of an appropriate level of quality by Victorian pathology service providers. Further, the Review Panel is of the view that these initiatives will provide for a less restrictive and less costly arrangement than the current regulatory system, while protecting public health.

I commend this report to you.

Yours sincerely

A handwritten signature in black ink, appearing to read "Don Nardella". The signature is fluid and cursive, with a large initial "D".

Don Nardella MLA
Chair
Pathology Services Accreditation Legislation Review

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Abbreviations and Acronyms

AS/ISO	Australian Standard/International Organisation for Standardisation
CDH&A	Commonwealth Department of Health and Ageing
CoAG	Council of Australian Governments
HIC	Health Insurance Commission
HSC	Health Services Commissioner
NATA	National Association of Testing Authorities, Australia
NCP	National Competition Policy
NPAAC	National Pathology Accreditation Advisory Council
OECD	Organisation for Economic Co-operation 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

1. The Review Process

1.1 Establishment of the review

In October 2000, the then Minister for Health, the Hon John Thwaites MP, commissioned a review of the *Pathology Services Accreditation Act 1984* (the Act) in accordance with the Victorian Government's commitments under the National Competition Policy (NCP) Agreements. Under the NCP Agreements, governments are required to review legislation in accordance with the 'guiding legislative principle'. That is, the principle that legislation 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 (Competition Principles Agreement, Clause 5(1), cited in Department of Premier and Cabinet, 1996a).

NCP does not demand that competition should take precedence over the public interest nor does it equate competition with the public good. Instead, the NCP's guiding principle for all legislative reviews effectively requires that they establish 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 (Phillips Fox and Casemix Consulting, 1999).

To ensure that the review was conducted in a manner consistent with legislative reviews undertaken across all portfolios, the terms of reference for the review (see Appendix A) required that it comply with the Victorian Government's *Guidelines for the Review of Legislative Restrictions on Competition* (the guidelines) (Department of Premier and Cabinet, 1996b). The review was conducted as a semi-public review, the model for which is described in the guidelines, and was undertaken by an independent panel, chaired by Mr Don Nardella MP, Member for Melton. Members of the panel were:

Dr Chee-Wah Cheah	Principal, LECG Asia Pacific
Professor Stephen Cordner	Director, Victorian Institute of Forensic Pathology
Ms Kay Currie	Consumer representative, Chairperson, Health Issues Centre
Dr Graham Rouch	Consultant

Associate Professor Gordon Whyte assisted the Review Panel as technical advisor.

Once convened the Review Panel set about its task by meeting with a number of individuals and organisations, each associated with the pathology services industry as either regulators or as those who are regulated. These meetings greatly assisted in informing the review and the Review Panel acknowledges the openness with which discussions were conducted and would like to thank all those who generously gave their time to contribute to the review process in this way.

1.2 Scope of the review

While the imperative to meet the Victorian Government's obligations under the NCP Agreements provided the impetus for the review, the Review Panel determined it was appropriate and necessary to undertake a wider review of the legislation and its role within the context of the broader health care system. The Review Panel was mindful that the environment within which pathology services operate has changed substantially since the Pathology Services Accreditation Act was assented to in 1984.

Technological developments have advanced the breadth and sophistication of clinical care, including pathology testing. Consumers have become increasingly aware of their rights to information, and of health issues generally, 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 expanded and has become increasingly dominated by large, private sector organisations. Moreover, the regulation of the industry is substantially different from that envisaged at the time of the passage of the Act. The expected adoption of similar legislation in other States and Territories of Australia has not eventuated, and the Commonwealth has introduced an Australia-wide accreditation mechanism for Medicare remunerated pathology services, which comprise the bulk of the industry.



As part of its desire to approach the review of the legislation from a broader perspective, the Review Panel was mindful to ensure that the existing legislation was assessed against widely held principles of good regulation. Such an assessment would ensure the review was cognisant of the Victorian Government's wider commitment to implement regulatory best practices in the public interest. The Review Panel identified the two main sources of these principles, namely the Council of the Organisation for Economic Co-operation and Development's (OECD) Recommendation on Improving the Quality of Government Regulation (OECD, 1995) and the Council of Australian Governments' (CoAG) *Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies* (CoAG, 1997). In addition, CoAG (1997) has published other guidance material on good regulation that was also taken into account by the Review Panel¹.

During the course of the review, the *Pathology Services Accreditation (General) Regulations 1990* and *Pathology Services (Exempted Tests) Regulations 1990* were to sunset under the *Subordinate Legislation Act 1994*². To avoid a regulatory hiatus and allow the review of the Act to proceed, proposed replacement regulations and accompanying Regulatory Impact Statement (RIS) (Jaguar Consulting Pty Ltd, 2001) were drafted and circulated for public comment. In comparison with the regulations being replaced, the new regulations contained the minimum necessary change. The Minister for Health took the view that as the Act was being reviewed, it was prudent to ensure the stability and predictability of the regulatory environment and eliminate the possibility of two significant sets of regulatory changes occurring within a short period.

1. These materials were discussed in the Review Panel's Discussion Paper (Pathology Services Accreditation Legislation Review, 2001:4-6).

2. The Subordinate Legislation Act provides that all statutory rules shall sunset ten years after coming into operation. The regulations were extended in operation by one year by means of the *Subordinate Legislation (Pathology Services Accreditation (General) Regulations 1990 – Extension of Operation) Regulations 2000*, S.R. No. 8/2000 and the *Subordinate Legislation (Pathology Services (Exempted Tests) Regulations 1990 – Extension of Operation) Regulations 2000*, S.R. No. 7/2000. These extensions were authorised by sections 5(3) and 5(4) of the Subordinate Legislation Act.

All the responses to the RIS raised issues considered appropriate for the Review Panel to explore as part of the review of the Act. For this reason, those consulted during the course of drafting the regulations and the submissions to the RIS have been included in the list of submissions to the review (see Appendix B).

1.3 Release of discussion paper



In May 2001, the Review Panel released a Discussion Paper (Pathology Services Accreditation Legislation Review, 2001) to enable an informed discussion to occur on the current Victorian legislative model governing the pathology services industry. Copies of the Discussion Paper were disseminated to all pathology services accredited with the Victorian Pathology Services Accreditation Board (PSAB), all relevant learned colleges and professional associations, industry representatives, public hospitals and metropolitan health services, Commonwealth, State and

Territory Health Departments, the Victorian Health Services Commissioner and relevant University Faculties. Public notices of the review and calls for submissions were advertised in major Victorian and national newspapers and a copy of the Discussion Paper was placed on the Department of Human Services' website.

A number of questions were raised in the Discussion Paper. These questions were intended to stimulate broader thinking and discussion about the current Victorian accreditation system. The questions included whether the Victorian accreditation system serves the public interest, questions about 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. The Discussion Paper also sought quantitative data and methodological comments in relation to the options posed and the size of the potential public risk associated with pathology services.

Responses to the Discussion Paper were received from a variety of interested parties and the Review Panel has sincerely appreciated the efforts made by individuals and organisations in this regard. Unfortunately, the responses to the Discussion Paper provided little in the way of quantitative data. However, they provided qualitative information and opinions on many specific aspects of the Victorian legislative model and, in many cases, commented on the operation of the industry, and its system of accreditation, as a whole. The issues that provoked the most vigorous responses were:

- whether a State-based accreditation régime for pathology services provides additional protection for consumers over and above the protections inherent in the Commonwealth accreditation scheme;
- the question of how consumer safety can be assured if testing is performed in an unregulated environment;
- the impact of advances in technology, such as 'point of care testing', and the inability of regulation to keep pace with change;

- the nature of some of the tests listed as ‘exempted tests’ and whether their exempt status should be maintained. Conversely, whether other tests, such as cholesterol testing, should be included in the schedule of exempted tests;
- discrepancies between State and Commonwealth requirements governing the supervision of testing; and
- the structure and role of the PSAB.

The key arguments made in each of the submissions received and the comments made in meetings with the Review Panel have been examined and responded to in this Final Report. Informed by these arguments and comments and its own research, the Review Panel has made a series of recommendations concerning the regulation of the Victorian pathology services industry. The recommendations of the Review Panel have been based upon the findings of the Review Panel and do not necessarily represent the view of the Department of Human Services or the Victorian Government.



2. Description of the industry and the legislative restrictions on competition

2.1 Profile of the Victorian pathology services industry and its regulation



Chapters 2 and 3 of the Discussion Paper provided an overview of the pathology services industry and its provision of services. In the Discussion Paper the Review Panel also considered what ‘pathology’ and ‘pathology services’ are understood to entail and sought to describe the industry as it currently exists. To ensure this Final Report focuses on the outcomes of the public discussion process and on the recommendations of the Review Panel, generally, the detailed information contained in the Discussion Paper will not be repeated. Hence, for completeness, this Final Report should be read in conjunction with the Discussion Paper. A brief restatement of some of the key elements of the Discussion Paper’s description of the structure of the industry has been included below to highlight major issues analysed herein.

The pathology services industry can be divided into public and private sectors, and there are various settings for pathology services and various roles for pathologists in the delivery of patient care in each sector. The distinction between public sector and private sector pathology services was made on the basis of the sources of financing, as opposed to the regulation of service provision. In terms of regulation, both sectors are treated in the same way. While the Commonwealth regulates service provision throughout Australia, only in Victoria does the State also have a regulatory role.

In describing the existing regulatory arrangements for the Victorian industry, the Discussion Paper outlined the development of pathology services accreditation systems by the Commonwealth and Victorian Governments and provided an overview of the respective accreditation régimes. The key features of the Commonwealth and Victorian legislation and the key difference between the two régimes were highlighted.

The Commonwealth’s purview extends only to those pathology services for which a Medicare benefit is sought, while the Victorian legislation is concerned with pathology services eligible for Medicare rebates as well as those services that are either ineligible for access, or do not seek access, to such rebates. This difference between the two accreditation systems underpinned much of the PSAB’s submission. According to the PSAB, the

...chief and general benefit flowing from State accreditation is that consumers of pathology services in Victoria, unlike consumers in other States, have a guarantee that all pathology services are meeting certain basic standards with respect to the safety and accuracy of testing.

The universality of the Victorian accreditation system, suggests the PSAB, “...stands in stark contrast to the limited coverage of the Commonwealth’s scheme”.

Much was written in the Discussion Paper about the operation, in Victoria, of a 'dual' system of accreditation for the majority of pathology services. This issue was a key focus of a number of submissions and the arguments raised by respondents have been presented and analysed here in chapter 5.

In preparing the Discussion Paper's account of the Victorian pathology services industry, the Review Panel drew on a range of sources. These sources included a review of the current legislation, the report of the earlier review conducted by the Department of Health and Community Services (1995), the PSAB's submission (1994) to that review and discussions with industry representatives, the Commonwealth Department of Health and Ageing (CDH&A), including representatives of the National Pathology Accreditation Advisory Council (NPAAC), and the National Association of Testing Authorities (NATA).



The Review Panel anticipated that the public submissions process would enable a more detailed picture of the Victorian pathology services industry to emerge, including the level of service provision by the public and private sectors respectively.

As explained in the Discussion Paper, current, comprehensive data on service provision, by sector, is difficult to obtain. While the Commonwealth makes available data on pathology services (tests) for which Medicare benefits are paid, the data set does not account for all pathology tests provided in Australia. The Commonwealth does not collect data on pathology tests for which a Medicare benefit is not paid, such as pathology tests undertaken for employment-related health screening. Further, neither the Commonwealth nor the State routinely collects data on pathology tests provided for patients admitted to Victorian public hospitals as public patients, or those pathology tests provided for non-admitted public patients whose outpatient attendances are funded under the Victorian Ambulatory Classification System.

In considering the costs and benefits of the current legislation, a clear view of the composition of the pathology industry is fundamental. In particular, given the existence of an accreditation scheme at the Commonwealth level, it is essential to understand the number and nature of pathology services that are subject only to the Victorian scheme. In the Discussion Paper, the Review Panel sought to identify the number and types of services accredited solely under the Victorian régime, as opposed to those holding dual Commonwealth and Victorian accreditation. On the basis of the information available at the time, the Review Panel estimated that, overall, the Victorian scheme accredited 42 more services than the Commonwealth's scheme (Pathology Services Accreditation Legislation Review, 2001: 21, Table 3.2). This suggested that around 24 per cent of the total number of pathology services accredited in Victoria were not accredited at the Commonwealth level. At the time, the Review Panel was satisfied this difference in the number of services could be attributed to the Commonwealth's legislation requiring accreditation only for those pathology services seeking Medicare rebates for patients.

Several submissions commented on the number and scope of pathology services that operate in Victoria without Commonwealth accreditation. For instance, the Medical Scientists' Association of Victoria stated that

Almost a third (31%) (sic) of the pathology services registered in Victoria are not registered by the Health Insurance Commission. These are laboratories, which charge patients directly for their tests or have other sources of funding. They include:

- Screening clinics (e.g. cholesterol, glucose)
- OH&S Clinics
- Red Cross Blood Bank
- Workplace testing (e.g. for substances of abuse)
- Alternative health care providers
- Research laboratories
- Reference laboratories
- Sports medicine clinics.



While the Review Panel appreciated that the majority of respondents were not in a position to ascertain the accuracy of the Review Panel's initial estimation, some used this figure unquestioningly to base vigorous arguments supporting the universality of the Victorian accreditation system. The Australasian Association of Clinical Biochemists Inc. – Victorian Branch, for instance, argued that

42 out of 170 pathology services in Victoria (31%) (sic) are not accredited under the HIC and if the PSAB were disbanded would not have to meet any minimum standards. The numbers or quality of such services outside Victoria is not known, but it is almost certainly of much higher numbers of services and lower quality than in Victoria.

As the PSAB's submission did not challenge the assumptions contained in the Discussion Paper, the Review Panel subsequently sought its assistance to formulate a more precise estimation of the number and type of pathology services accredited only under the Victorian legislation. The information subsequently obtained from the PSAB indicated that the Discussion Paper's initial estimate of 42 services accredited only in Victoria substantially exceeded the true number³. According to the data supplied by the PSAB, as at October 2001, there were 21 services accredited solely under the Victorian Act. The Review Panel subsequently learned that of the services so identified by the PSAB:

- two are arguably on the same premises;
- one is also accredited under the Commonwealth's system for Medicare purposes; and
- another is located on Commonwealth Territory and may therefore be beyond the jurisdictional reach of the Victorian legislation.

3. The Health Insurance Commission (HIC) implemented a new classification system for pathology services, effective from 1 January 2000, comprising five service categories. The number of accredited laboratories reported by the Commonwealth under this classification system in December 2000 was 137. To ensure consistency with the classification changes introduced by the Commonwealth, equivalent changes to the Victorian classification system for pathology services were made effective by Governor in Council on 26 February 2001. Since the Victorian changes were introduced, the allocation of services to the new classifications has occurred progressively as services have applied for renewal of their accreditation. Prior to the Victorian changes being introduced, the PSAB reported (in September 2000) a total of 179 accredited laboratories.

This suggests a true figure of either 18 or 19 services accredited only in Victoria. Broadly speaking, these pathology services belong to three categories:

(i) Health screening services

Twelve of these pathology services provide testing of a narrow range of health indicators. Ten services provide preliminary health screening services for cholesterol and lipids and the remaining two services provide specialised screening for the presence of metals (for instance: cadmium, mercury and lead) in blood and urine samples and for the detection of substance abuse. Both services operate under contract for certain industries and, generally, testing is conducted in accordance with occupational health and safety legislative requirements.



Services in this group comprise three public sector providers (Community Health Centres) and nine private sector providers (including two Category M services⁴).

(ii) Genetic testing services

Two of these pathology services provide genetic testing. Both providers are public sector services and are associated with major public teaching hospitals.

(iii) Other services

The five remaining pathology services conduct a range of specialised and mainstream pathology testing. Three are located in the public sector (one located within a major public teaching hospital and another associated with a university) and two are located in the private sector.

The specialised tests conducted by services in this group include:

- urea breath test for *Helicobacter pylori*;
- tests to diagnose immediate allergic reactions to pharmaceuticals;
- full range of oral pathology testing; and
- therapeutic monitoring of drugs.

4. Under the Pathology Services Accreditation Act, a Category M service is one in which tests, approved by the PSAB, are performed by, or under the supervision of, a registered medical practitioner only for patients of the medical practice in which the practitioner works (Schedule 1, Pathology Services Accreditation Act).

2.2 Identification of legislative restrictions on competition

The Discussion Paper outlined the restrictions on competition in the pathology services industry inherent in the existing legislation. To meet the specific requirements for reviews under the NCP Agreements, this Final Report restates the specific restrictions on competition contained in the current legislation identified in the Discussion Paper and then discusses the extent of their likely impact, given the structure of the pathology services industry, and considers whether the objectives underlying these restrictions can be met in any way that does not restrict competition. This Final Report also assesses the costs and benefits to the community of the restrictions on competition.



As the review was not limited to the issues of restriction on competition imposed by the legislation, this Final Report also addresses the broader legislative framework that encapsulates the pathology services industry and the role of the State in the regulation of pathology services *vis-à-vis* the Commonwealth's accreditation scheme for Medicare remunerated services.

In the Discussion Paper, the Review Panel identified those areas of the Act and regulations that could be said to be restricting competition – that is, creating unnecessary barriers, stifling innovation, limiting consumer choice and/or reducing incentives to improve efficiency. In summary, the provisions can be grouped under two key areas:

(i) Barriers to entry

- requirement for 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;
- specification of minimum qualifications for persons performing pathology tests; and
- restriction on the number of pathology services of which a person can be in charge.

(ii) Regulation of minimum standards and restriction on conduct

- specification of minimum standards for matters including staff, facilities, equipment, quality control and reporting;
- prohibitions on advertising; and
- prohibition on the performance of certain tests.

The next chapter provides an analysis of the anti-competitive provisions of the Act and regulations.

3. Analysis of the legislated restrictions on competition

3.1 Requirement for accreditation of services

Part IV of the Pathology Services Accreditation Act prescribes the requirements for accreditation including:

- arrangements for inspections by an approved inspection agency,
- limitations on who can be in charge of a pathology service;
- establishment of categories of accredited pathology services; and
- powers to suspend or cancel the accreditation of a pathology service.



In general terms, the use of an accreditation system can be seen to be appropriate where substantial health risks can result from poor performance. This is clearly the case with a wide range of pathology services, although it does not appear to be true of all such services. However, even if an accreditation system is considered to be appropriate, under the NCP and the principles of good regulation, the question of whether its requirements are the minimum necessary to achieve the regulatory objective must be considered.

Barriers to entry

The requirement for accreditation imposes no *absolute* barrier to entry, insofar as there is no limitation on the numbers of services able to be accredited. However, such a barrier exists in that no person may be in charge of more than three pathology services (section 13 (3) (b) of the Act) and only a pathologist, medical practitioner or a scientist, holding specific qualifications, may be in charge of a pathology service (section 13 (3) (a) of the Act and regulation 7 of the *Pathology Services Accreditation (General) Regulations 2001*).

The size of the barrier to entry imposed by an accreditation system depends on the specific requirements for accreditation and their relative importance in the context of the businesses that seek to be accredited. The Act's accreditation requirements are considerable, and can be divided into 'substantive' and 'procedural'. In the former category are the requirements to meet minimum standards in relation to equipment and premises, testing procedures, record keeping and staff qualifications. In the latter category are the requirements for inspections by National Association of Testing Authorities (NATA)/Royal Australian College of General Practitioners (RACGP) assessors, as well as the paperwork burdens involved and the fees payable.

An analysis of both the absolute barrier and the size of the barrier imposed by accreditation must distinguish between services accredited under the Commonwealth's system for Medicare purposes and those that are not. Evidence provided to the Review Panel has shown Victorian accreditation procedures and requirements (including minimum standards for equipment, facilities, testing, staffing and the like) have, in the main, been quite consciously aligned as closely as possible with

their Commonwealth equivalents to reduce inconsistencies and the associated additional burdens that would arise (PSAB; Department of Health & Community Services, 1995; PSAB, 1994).

Laboratories holding dual Commonwealth and State accreditation, in general, have stated to the Review Panel that, other than requirements relating to the supervision of staff, Victorian accreditation does not compel them to meet additional substantive requirements and that the marginal burden to them of the Victorian system is essentially limited to procedural requirements. One indication of the effect of the conscious alignment of the two sets of standards is that a single inspection by NATA/RACGP assessors is able to serve both Victorian and Commonwealth requirements. Hence, other than staff supervision requirements, the additional burden of the Victorian accreditation requirement for dual accredited laboratories is merely that of additional paperwork, plus the fees involved. Aside from staff supervision requirement (which will be considered later), the size of the restriction on competition imposed on this group, as a result of the accreditation requirement, must be considered minimal, at least within the context of the presumed continuation of the Commonwealth's accreditation system.



The position is substantially different for those pathology service providers accredited only in Victoria. For this group, the accreditation requirements attributable to the Victorian Act include the full set of substantive and procedural requirements noted above. The Review Panel's enquiries revealed that this group is relatively small in number (see above) and is largely comprised of small-scale services (compared with the majority of services that are accredited with the Commonwealth for Medicare purposes) that specialise in the provision of a narrow range of tests. As noted above, approximately two thirds of service providers in this group conduct health-screening services for a narrow range of health indicators, such as cholesterol.

Evidence from pathology services among this group has indicated that the accreditation requirements are regarded as substantial and costly. Several providers told the Review Panel the accreditation requirements have the effect of substantially reducing the number of service providers in this group. For instance, an accredited provider of cholesterol screening services stated that many comparable organisations are providing, or would like to expand their services to provide, cholesterol-screening services, but have been dissuaded by the accreditation requirements from seeking accreditation. Another example was given in which a provider of cholesterol screening services decided to withdraw from the market following a management review of the ongoing costs of meeting accreditation requirements. The service was subsequently sub-contracted to a former competitor, and the proposed withdrawal from the market was avoided.

Examples such as these, together with the picture the Review Panel formed of the nature of the 'Victorian only' accredited sector have led the Review Panel to conclude that the restriction on competition provided by the accreditation requirement is likely to be substantial in its effect. Unfortunately, data on the number of providers of non-Commonwealth accredited pathology services operating in other the States and Territories of Australia (in which there are no state-based accreditation requirements)

are not available. Thus, it has not been possible for the Review Panel to verify its conclusion quantitatively by comparing the number of providers in different sectors across States and Territories. It is the clear view of many industry participants, however, that the accreditation requirements are likely to have reduced substantially the numbers of such services operating in Victoria.

A substantial reduction in the supply of service providers would, a priori, be expected to increase the price of the service. However, many health-screening services are provided either as ancillary services or as part of public health promotion initiatives. Thus, it may be that the effect on price of the reduction in supply is, in this context, limited. In fact, the Review Panel has understood that a high proportion of such screening tests are actually provided free of charge to the consumer.

Evidence presented to the Review Panel suggested that the more important likely effect of the reduction in the supply of service providers is that of reduced access to services. In this context, it has been argued enhanced up-take of screening tests by consumers is an important way of improving public health outcomes and decreasing, in the long term, the cost burden on the health care system (Centre for Advancement of Men's Health and Hepburn Health Service). However, part of the challenge that health promoters, for instance, face in encouraging individuals to participate in health promotion screenings is targeting appropriate settings – such as workplaces or convenient and accessible locations within a community (Centre for Advancement of Men's Health and Hepburn Health Service). In this regard, restricting the supply of service providers would be likely to reduce the rate of participation in health promotion screenings, rather than switching demand to other providers.

In conclusion, the impact on competition of the accreditation requirements is likely to be substantial, but confined to small-scale organisations. The question of whether the objectives of the legislation can be achieved in ways less restrictive on competition is considered in chapter 4.

3.2 Prohibition on purporting to be an accredited pathology service when not accredited

This can be considered a corollary of the accreditation requirement, discussed above, rather than a separate restriction on competition. The restriction does not impose additional restriction on competition, over and above that imposed by the accreditation requirement. Rather, its effect is as a part of the enforcement of the primary restriction – that of requiring accreditation. Thus, its impact will not be analysed separately.



3.3 Categorisation of services and the specification of minimum qualifications for persons in charge of a pathology service and for persons conducting tests

3.3.1 Description of restrictions

Under the Victorian and Commonwealth accreditation schemes, laboratories are grouped into five categories with each category defined according to the type of testing performed and the level of supervision required on a day-to-day basis⁵.

In its submission, the PSAB advised that “categorization also facilitates the inspection of laboratories and selection of inspection teams” and that the wording of the descriptions of the categories is so broad the majority of pathology services are adequately captured. Victorian pathology services are assigned to Category G (General), B (Branch), M (Medical Practitioner), S (Specialised) or, in the event none

of these is suitable, Category U (Unspecified).

The Act requires the ‘person in charge’ of a pathology service be a pathologist, a medical practitioner or a scientist⁶. It also makes a number of other stipulations in regard to the qualifications of managers and the availability of supervision. These requirements vary according to the category to which the pathology service has been assigned, namely:

- Category G⁷ services must have “...direct, full-time or equivalent full-time professional and scientific accountability and supervision by a pathologist or pathologists or by a scientist or scientists” (Schedule 1, Pathology Services Accreditation Act); and
- Category B⁸ services “...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...” (Schedule 1, Pathology Services Accreditation Act).

5. As indicated earlier, this classification system was recently adopted by the HIC to replace the pre-existing classification system and has been adopted progressively by the PSAB.

6. The qualifications required by the Act for those in charge of a pathology service align closely with those requirements specified by the National Pathology Accreditation Advisory Council (NPAAC), namely that:

- A pathologist is a person who is a medical practitioner with a higher qualification in pathology recognized by the National Specialist Qualification Advisory Committee of Australia.
- A medical practitioner is a person who is registered under the *Medical Practice Act 1994*
- 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 PSAB's opinion is a qualification equivalent to that outlined in (i) or (ii).

7. 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.

8. 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.

If the person in charge of a Category G or B service is a scientist, then the regulations specify that the scientist must:

- have a postgraduate qualification in a science prescribed in Schedule 2 of the Act and five years experience working in a pathology service since obtaining the postgraduate qualification; or
- have at least 10 years experience working in a pathology service since obtaining the qualification referred to in the Act's definition of 'scientist'.

For Category M services, the regulations limit the position of 'person in charge' of such a service to a medical practitioner.

Those services assigned to Categories S and U are required by the regulations to appoint, as the person in charge, a medical practitioner, pathologist or scientist. In particular, tests conducted by Category S services, the range of which is limited to those tests approved by the PSAB and conducted on a particular target population or are of a specialised nature, are those which must be "...performed under the supervision of a person having special qualifications or skills...in the field of [the specialised tests performed]" (Schedule 1, Pathology Services Accreditation Act).



The regulations also specify certain minimum qualifications for persons conducting pathology tests. Generally, the regulations require, as a minimum, persons conducting tests in any category of pathology service be a medical practitioner, pathologist or scientist. However, the regulations also provide flexibility by not prescribing any minimum qualification for persons conducting tests in a:

- Category M service, if the person is performing the test under the supervision of a medical practitioner;
- Category U service, if the person is performing the test under the supervision of a medical practitioner, pathologist or scientist;
- Category G, B or S service, if the test is performed under the direct supervision of a medical practitioner, pathologist or scientist who –
 - (i) is qualified in the relevant division of pathology; or
 - (ii) has conducted tests of that kind for an aggregate period of at least one year during the 5 years before commencement of the supervision.

3.3.2 Analysis of restrictions

The specification of minimum qualification requirements can be said to be justifiable where there are substantial public health issues at stake, as is the case for most, though not all, pathology testing. However, two issues arise in respect of these restrictions, namely, the 'two tiered' nature of the restrictions and the technological changes in pathology testing.

'Two tiered' nature of the restrictions

The Act and regulations specify minimum qualifications for staff and management. Such a 'two tiered' approach can be seen as duplicative in nature and to confuse the question of responsibility

for testing standards. It is arguable that, if the person in charge is considered to be technically expert and ultimately responsible for quality outcomes, regulators should rely on that person's discretion as to the appropriate staff to employ to conduct testing. This point may be particularly pertinent in relation to the technological issues discussed below.



Alternatively, the view could be taken that the requirement for qualified persons to conduct testing effectively places responsibility for technical quality issues at this point. Despite the significance of the quality issues involved, the fact that substantial qualification requirements are in place at this level could reasonably be seen as meeting these concerns. On this view, requiring the 'person in charge' to be technically qualified is unnecessary⁹ and may have negative impacts on pathology services by reducing their opportunity to be directed by people with expertise in management, marketing or other disciplines vital to the services' success as businesses. In line with this view, legislation elsewhere emphasises quality assurance based approaches to maintaining the integrity of testing results. This suggests that the necessary role of the person in charge is more systems and management focused than technically focused, as the skills required to implement an effective quality assurance system are, to a large extent, managerial and process based.

Despite the issue of the 'two tier' nature of the qualification requirements being raised in the Discussion Paper (see pp 24-25 and discussion questions 4.6 and 4.7), no submission directly addressed this.

Technological changes in pathology testing

Evidence presented to the Review Panel indicated there had been, and continues to be, substantial technologically driven changes in pathology practice in recent years, and these have had and continue to have significant implications for the question of qualification and supervisory requirements (for instance, submissions from the International Diabetes Institute; Peter MacCallum Cancer Institute; Eastern Health).

Evidence presented to the Review Panel suggested a considerable number of tests conducted within laboratory-based settings are now substantially automated and this has had the effect of reducing the skill requirements for those conducting the tests. For instance, in its submission, Eastern Health suggested that

The vast majority of pathology tests, particularly in the disciplines of chemical pathology (biochemistry) and haematology, are performed by sophisticated automated analysers with on-board computers linked to laboratory information systems capable of data validation and ensuring quality assurance.

9. It should be noted that the current legislation does not necessarily imply a 'two tiered' set of technical requirements, to the extent that the 'person in charge' and the person supervising unqualified people in the conduct of tests can be the same person. Thus, the criticism of the Act on these grounds can be seen as largely inapplicable to small laboratories.

Further, Eastern Health argued that

...appropriately trained persons with qualifications less than those required for the definition of a medical laboratory scientist e.g. medical laboratory technologists, are suitable operators of pathology analysers in an expanding number of employment contexts realising significant efficiency gains with no impact on quality... It is likely that these efficiency gains have not been realised in Victoria relative to other Australian States and that, at least in part, this is due to the Regulations of the Pathology Services Accreditation Act and the definition of direct supervision as interpreted by the [PSAB].

The Discussion Paper raised the issue of the Victorian legislation's supervisory requirements, particularly the requirement for 'direct supervision' of staff conducting tests. Several submissions called for the discrepancy between the Victorian and Commonwealth requirements to be removed as advances in electronic communications enable satisfactory remote access to laboratories and improvements in testing equipment, in many cases, obviate the need for constant, direct supervision of staff operating such equipment, particularly outside of normal working hours.



As far as the arguments presented are correct, the qualification and supervisory requirements can be seen to impose unwarranted additional labour costs on pathology services to the extent they have not been varied to take proper account of the changes noted above. To the Review Panel's knowledge, there have been no changes to the legislation's qualification requirements in recent years in response to these developments.

Further evidence was presented to the Review Panel in relation to the technologies that enable testing to shift away from the laboratory to those settings where direct patient care is provided. Several respondents argued that new technologies that can be used at the point of care by staff who may not be qualified to undertake traditional laboratory roles can provide substantial economic advantage, while preserving and even improving accuracy levels. However, a number of respondents qualified their support for the adoption of point of care testing technologies by arguing that staff conducting point of care testing nonetheless needed to be appropriately trained and supervised, that tests results should be documented in the patient record, and that some form of regular accreditation should be applied, along with a requirement for participation in an external quality assurance program (Eastern Health; Peter MacCallum Cancer Institute; Alfred Pathology Service).

Respondents also raised concerns about what they saw as the demonstrated inability of the existing legislation to keep pace with technological changes. Hospital respondents in particular expressed concern that the Victorian legislation stifles innovation and hospitals' ability to realise efficiency and quality gains through the use of point of care testing (Eastern Health; Peter MacCallum Cancer Institute; Mayne Health; The Victorian Healthcare Association Ltd.). One respondent suggested that under the current legislation, hospitals are unable to provide point of care testing by using appropriately trained nursing staff without, at a minimum, a grade 1 scientist being present in the hospital at the time of testing. As the Victorian legislation requires a Category G service to ensure

that direct supervision is provided at all times, to meet this cost outside of normal working hours, this imposes an additional cost to the laboratory in the order of \$86,000 *per annum*.

If these arguments are valid, the current qualification and supervisory requirements impose unwarranted additional labour costs on pathology services to the extent that they have not been varied to take proper account of the technologies that enable point of care testing to be conducted.



The PSAB's submission did not discuss the reasons it considers off-site supervision inappropriate, nor did it detail its concerns regarding point of care testing within the above context. Instead, the PSAB argued that "...the more specific requirements of the Victorian Regulations (in contrast to the requirements of the Commonwealth scheme) have been influential in deterring pathology services in Victoria from employing staff without appropriate qualifications to perform testing outside of normal operating hours". Nonetheless, the PSAB recognised more generally that

technological advances and changes in pathology practice must of necessity lead to reappraisal of requirements to see whether they are continuing to serve a useful purpose. The advent of near-patient testing in hospitals will necessitate re-examination of the requirements of the Regulations as they...relate to out-of hours testing.

The Review Panel has been unaware of any evidence to suggest that, as a result of the PSAB's current approach to these issues, pathology testing in Victoria is of a higher standard than elsewhere in Australia. By contrast, evidence presented to the Review Panel argued strongly that the current PSAB approach has imposed significant and growing costs on the industry.

3.4 Limitation on the number of pathology services of which one can be 'in charge'

The Act sets an upper limit of three on the number of pathology services of which a person can be 'in charge'. Given the Act's and the PSAB's emphasis on issues of supervision, it can be deduced that the purpose of this restriction is to ensure that the person in charge is able to take an active involvement in the day to day running of the pathology service. This restriction can be seen as consistent with the requirement that the person in charge should be technically qualified in a pathology-related discipline, as both restrictions are predicated on a presumption of the ultimate responsibility of the person in charge for the quality of testing. Consequently, this restriction must also be viewed in the context of the discussion of the 'two tiered' approach to qualification requirements, presented above. That is, such a restriction could only be seen to have potential merit in a context in which the problem of duplicated responsibility, noted above, were resolved in favour of placing the primary responsibility with the person 'in charge' of the pathology service.



However, even in this context, there are grounds for questioning the ability of such a restriction to contribute to improved quality outcomes. It is clear that a person in charge of three pathology services would be limited in his or her capacity to supervise the quality of testing conducted from day to day, particularly where the services involved are of large scale. In this context, the recent consolidation in the industry must be noted. This process of consolidation has meant a few very large testing facilities now conduct vast numbers of tests on samples collected from substantial numbers of collection centres. In this context, a prohibition on being 'in charge' of more than three such testing facilities is essentially meaningless in practice. Hence, there is some question as to whether this restriction serves any substantial purpose.

Of the submissions received, only that from the PSAB commented on this restriction. In the PSAB's view, advances in technology and changes in supervisory practices have now made this provision redundant. The Review Panel received insufficient information to allow firm conclusions to be drawn regarding the effects of this restriction on competition. However, given the information available, it is considered unlikely the prohibition on a person being in charge of more than three pathology services has a substantial impact in lessening competition. However, while the costs of this restriction on competition are likely to be minimal, it is also likely the benefits of the restriction may be similarly inconsiderable.

3.5 Specification of minimum standards for matters including staff, facilities, equipment, quality control and reporting

As explained in the Discussion Paper, 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 (OH&S) aspects of the operation of pathology services extends, in part, to the regulations setting out detailed

requirements in relation to matters such as storage facilities, bench space, equipment, emergency power, water supply and staff amenities. The regulations also cover other aspects governing the operation of pathology services including staffing levels, obligations to have quality assurance systems in place and reporting requirements. In addition, the regulations refer to more detailed requirements set out in documents published by NPAAC and Standards Australia.



The regulations constitute a highly detailed, 'command and control' approach to the goal of ensuring pathology services are adequately equipped to provide high quality testing, with proper standards of practice and technical procedures being observed routinely, as well as the secondary goal of encouraging the use of safe working practices. The complexity and prescriptive nature of these requirements are likely to have a substantive impact on competition in the industry by posing a barrier to entry to prospective providers. This effect would operate because of the task of mastering the regulatory complexities involved and the need to reach substantive compliance with the provisions. In considering whether the degree of the restriction on competition is justified, a judgment must be made as to whether the requirements are the minimum necessary to achieve the objective of assuring high quality pathology services. In reaching a conclusion on this issue of necessity, the following must be considered:

- First, these prescriptive requirements operate in the context of substantial requirements as to the professional qualifications of both testers and managers of pathology services. In light of this, and the context of regular, detailed inspections and reporting by NATA assessors, there is necessarily a question of whether the requirements are more onerous than necessary, given the possible alternative of adopting a more flexible, performance oriented approach, which recognises the high level of professional qualifications that other parts of the legislation demand of pathology service providers. There appears to be potential for these prescriptive requirements to constitute significant anti-competitive barriers toward small, specialised services, in particular, while the offsetting benefits are not apparent.

- Secondly, the regulation of these matters fails the test of being the minimum necessary to the extent that it duplicates requirements set elsewhere. The Medical Scientists' Association of Victoria provided an extract of material in its submission to demonstrate "...how the majority of regulations, standards and guidelines used by the PSAB are actually set by other authorities". As noted above, the requirements governing the qualifications of management and staff and the supervision of staff conducting tests are closely aligned with those requirements set by NPAAC. This alignment with Commonwealth standards extends to matters such as bench space, emergency power, equipment (including blood bank refrigeration equipment), procedures such as recording and maintaining results of specimen testing and the provision of a methods manual. In addition to NPAAC standards, some of which are specifically referred to in the regulations, reference is also made to AS/ISO publications, specifically in relation to the establishment and participation in a quality management system. The Review Panel has noted that in the remaking of the pathology services regulations, the Department of Human Services was advised by Parliamentary Counsel to refrain from including a number of regulations, proposed by the PSAB, that duplicated existing provisions of the Building Code of Australia and the *Occupational Health and Safety Act 1985*.



As explained in the Discussion Paper, a new legislative structure governing OH&S has been passed since the commencement of the Pathology Services Accreditation Act. This commenced with the passage of the OH&S Act. The OH&S Act applies to all Victorian workplaces including Victorian pathology services. If the nature of pathology laboratories as workplaces is such that there are substantial pathology-specific OH&S issues to be regulated, this may provide a justification for the existence of pathology-specific OH&S provisions. However, two key characteristics of the OH&S Act militate against this.

First, the OH&S Act is written in broad, performance-oriented terms. It is based on the concept of the employer having a general duty to take all practicable steps to ensure the workplace is safe (section 23)¹⁰. Thus, the OH&S Act effectively applies to pathology laboratories as much as any other kind of workplace. As it is not based on specific, prescriptive requirements, any specificity in relation to the risks inherent in pathology laboratories does not necessarily undermine the effectiveness of the legislation.

Secondly, and closely related to the above point, section 55 of the OH&S Act provides powers for Codes of Practice to be adopted to provide practical guidance for the management of particular OH&S risks. Thus, were it considered necessary to manage pathology specific risks adequately, it would be possible for a Code of Practice to be adopted pursuant to this section.

The Review Panel has formed the view that much of the specific material in relation to staff, facilities, equipment and reporting standards goes beyond the minimum necessary to ensure the achievement of the objects of the Act. Alternative means of achieving these objects are considered further in the following chapter.

10. A parallel duty exists requiring employees to take all practicable steps within their control to ensure the safety of the workplace.

3.6 Restrictions on advertising

The legislation prohibits advertising that is false or misleading, advertising that compares pathology services and advertising that deprecates another service. While restrictions on advertising have potentially severe anti-competitive effects, the Review Panel has considered these controls to be minimal in nature and not likely to have substantial effects. For example, the prohibition on false or misleading advertising mirrors the general prohibition contained in trade practices legislation. The remaining prohibitions are unlikely to affect market conduct greatly and any harm is likely to be addressed by existing laws. For instance, advertising that seeks to damage the reputation of another business may fall foul of defamation law, or may be false or misleading.



In this context, the Review Panel has noted that the remade regulations did not reinstate a number of more detailed restrictions that had previously been in place and which *prima facie* had greater anti-competitive potential.

3.7 Competition issues pertaining to the regulation of specific tests

3.7.1 Prohibition on the performance of certain tests

In its submission, the PSAB contended that the

...chief and general benefit flowing from State accreditation is that consumers of pathology services in Victoria, unlike consumers in other States, have a guarantee that all pathology services are meeting certain basic standards with respect to the safety and accuracy of testing.

The universality of the Victorian accreditation system, the PSAB has suggested, "...stands in stark contrast to the limited coverage of the Commonwealth's scheme". Further, the PSAB argued that a "...serious deficiency [and the]...most glaring flaw in the coverage of Commonwealth accreditation is that it is powerless to prevent the performance and spread of pathology testing with little or no proven scientific validity".

In support of its argument, the PSAB submitted a case study to demonstrate how it was able to take action in relation to a service that was performing "...a range of unusual diagnostic tests"¹¹ and how, after the service failed to take remedial action to address the concerns of the PSAB, the PSAB made the decision to refuse the service accreditation.

11. The Review Panel has understood this to mean tests that, in Australia, are not considered as mainstream pathology tests.

The case study demonstrated that the PSAB acted swiftly to direct an unaccredited service to make application for accreditation. Accreditation was subsequently granted for the service to be "... a Category 6 service...only able to perform the tests for which it had been given approval by the Board". The case study explained that the

Promotional material distributed by the pathology service soon after it was given deemed accreditation showed that it was offering extra tests for which it had not sought Board approval. The Board instructed the service to seek approval for the extra tests. The service applied for and was given approval to conduct the extra tests. There were to be other instances where the pathology service strayed from the list of approved tests.

In addition to the service's failure to adhere to the conduct of only those tests that it was permitted to conduct, the PSAB explained it was also concerned about the service's overall standard of conduct. However, according to the PSAB, its major concern was that "...the service was offering tests of unproven scientific and clinical validity".

In reviewing the case study presented by the PSAB, the Review Panel was unable to find any provision in the Act or regulations that explicitly prohibits the performance of any tests not of established scientific or clinical validity. While section 40(1)(e) of the Act enables the Governor in Council to make regulations with respect to the tests or types of tests which may or may not be performed in particular categories of accredited pathology services, the Review Panel has been unaware of the existence of any such regulation.

3.7.2 Exempted tests

The Act includes provisions that operate at the level of individual pathology tests and the Review Panel has concluded they have an impact on competition. Provisions regarding individual tests are two-fold. First, individual tests can be declared to be 'exempted tests' and second, exempted tests can be declared to be 'non-regulated tests' and thereby not subject to any of the Act's restrictions.

Section 30 of the Act allows the Governor-in-Council, on the recommendation of the PSAB, to declare any test to be an exempted test. Section 30(2) provides that an exempted test may be performed by or under the supervision of:

- (a) a medical practitioner in the course of the medical practitioner's practice; or
- (b) 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.

Thus, medical practitioners and dentists are able to conduct exempted tests as part of the diagnosis and treatment of their patients.



The purpose of the exempted tests provision appears to be to make the Act more flexible by allowing certain tests to be performed outside the context of accredited pathology laboratories where the risks associated with so doing are considered to be sufficiently low. The provision of such a mechanism would appear to be an appropriate means of reducing the degree of restrictiveness of the Act and, at the margin, its impact on competition. However, several respondents argued that the choice of specific tests for inclusion among the list of exempted tests was inappropriate. While some of these respondents argued that certain tests were inappropriately included among exempted tests, others suggested the range of such tests was unduly narrow.



For example, Network Pathology, Austin & Repatriation Medical Centre expressed concern about the inclusion of tests such as differential white cell count and screening of blood film among the exempted tests. The argument made was that these are not simple screening tests and have far reaching clinical importance in diagnosing some malignancies, leukaemia and lymphomas and blood cell diseases.

Network Pathology, Austin & Repatriation Medical Centre argued that these tests should be regulated and performed by qualified and trained personnel.

Similarly, the Australasian Association of Clinical Biochemists Inc. argued that:

The [RACGP] and several 'health screening services' are currently requesting that cholesterol, haemoglobin A1c (HbA1c) and INR (a blood clotting indicator) become unregulated tests in a similar manner to glucose. Contrary to the statements from some commercial organisations and groups with a strong vested interest, there is no scientific evidence that these tests will provide reliable results outside of a regulated environment which mandates good quality control procedures. HbA1c as an indicator of glucose control in persons with diabetes, requires strict technical control of the testing process to provide reliable results. Similarly, both cholesterol and INR require a good technical knowledge and control of the testing instrumentation to ensure reliable results. Small deviations may give inaccurate results with a consequent misdiagnosis and/or inappropriate treatment. The small difference in results which may occur between perceived normality (or adequate therapy) and the level where clinical intervention (or altered therapy) is initiated, requires good control of the testing equipment to provide result data at the accuracy and precision level required.

In its response to the RIS, the RACGP Victoria had expressed concern about the limited range of exempted tests and argued that general practitioners should have a wider range of exempted tests available to them, including cholesterol, INR and HbA1c. This would enable them to improve screening and management of their patients with advantages to consumers by way of convenience and their health, with ultimate reductions in the health burden on our society and additional costs of attending pathology laboratories (that is, the payment of a collection fee in addition to the payment for the conduct of the test).

A difference in perspective appears to underlie these opposing opinions. Advocates of the wider use of exempted tests essentially see these tests being used for initial screening purposes, with an expectation of follow-up testing being carried out in a pathology laboratory where a probable cause for concern was indicated. Opponents appear to adopt the presumption that exempted tests would be used as an alternative to pathology laboratory based testing. This may be the reason there is clearly little consensus as to the appropriate breadth of the exempted tests arrangements. This is not surprising given there is clearly room for differing judgments in such an area. However, the PSAB's rationale for its decisions on the treatment tests in this regard is unclear and is not subject to public scrutiny. For instance, it was unclear to the Review Panel whether, in making decisions about which tests to recommend as exempted tests, the PSAB balanced the impacts on availability, and hence risks of the tests not being performed, against the potential risks of having them performed by personnel without specific training. Similarly, there appears to have been no regular or systematic review of the range of potential exempted tests over time to account for changes in technology and other factors that might require review of an initial decision.



3.7.3 Non-regulated tests

Section 30A of the Act, inserted in 1991, states that the Governor-in-Council may, on the recommendation of the PSAB, prescribe any exempted test to be a non-regulated test. The effect of such a prescription is that the Act's provisions do not apply in any way to the conduct of such tests. Thus, non-regulated tests are, as the name suggests, unregulated, whereas exempted tests can be considered to be 'partially regulated'.

As in the case of exempted tests, submissions to the review argued there were weaknesses in the choices made about what tests were to be prescribed as non-regulated. In particular, it was argued that common screening tests, such as those performed in relation to cholesterol and diabetes, should be non-regulated. Such arguments were based on several points:

- that the conduct of these tests is largely automated and little is required in the way of equipment or skills/training in order to ensure that they are administered properly and give accurate results;
- that, in any case, these tests were followed up by additional testing, conducted within pathology laboratories, wherever a screening result indicated cause for concern, thus providing additional quality control; and
- that a key public health risk was that of inadequate access to these screening tests, and that subjecting testers to the accreditation process reduced the availability of these tests and, hence, the contribution that they could make to public health.

The Review Panel found these arguments to be persuasive. As in the case of decisions about exempted tests, it has been unclear whether the rationale for recommendations about which tests should be non-regulated has been subject to public scrutiny and whether a benefit/cost-based

approach has been followed by the PSAB. As noted above, with regard to exempted tests, a benefit/cost-based approach would involve balancing the likely public health costs of reduced availability of such tests, were they to be regulated – and hence a reduced incidence of screening among risk groups in particular – against the public health costs of the test being performed poorly, in the event that they were unregulated.

Given the above, it is concluded that the Act appears to have been more restrictive in practice than could be justified on public benefit grounds.



4. Benefit/cost analysis of the Pathology Services Accreditation Act

The critical aspect of legislative reviews conducted under the requirements of the NCP is that regulation should only restrict competition in the public interest. In other words, the benefits of the regulation in terms of protecting the public must outweigh the costs of regulation – principally expressed in terms of restrictions on competition. This core principle does not imply that competition objectives should take precedence over the achievement of public policy objectives. Rather, what must be established is whether the objectives of the legislation can only be achieved by restricting competition, or if there are other, less restrictive means of achieving those objectives.



The objectives of the Act are not specifically related to the protection of the public. However, implied within the Act's principal objective of ensuring proper standards of practice and technical procedures are routinely observed in the conduct of pathology services, is the notion that the legislation serves to protect the public from risk associated with the conduct of pathology testing. The other objectives of the Act are to:

- ensure adequate standards of record keeping in pathology services;
- encourage the use of safe working practices in pathology services and to discourage unsafe or potentially unsafe practices; and
- ensure that staff employed in pathology services have had adequate and appropriate training.

This chapter explores whether there are appropriate, alternative mechanisms through which the objectives of the legislation can be achieved or whether these objectives can only be achieved through the use of a specific legislative framework. The discussion begins by considering whether the legislation provides any benefits to the Victorian community and if so, whether these benefits justify the legislative restrictions on competition. The Discussion Paper identified three ways in which these benefits could be assessed and these will be considered in turn. This chapter also considers whether the pathology services legislation provides additional protection for the community over and above the protection inherent in the Commonwealth's accreditation scheme for Medicare remunerated pathology services, and other regulatory and non-regulatory mechanisms that apply to the pathology services industry as well as other health service providers.

4.1 Estimating the benefits of regulation

As indicated above, the Discussion Paper identified three ways in which the benefits of the existing legislation could be estimated. The first suggestion was that indicators of the quality of pathology services provided could be compared in order to measure directly whether standards have improved since the adoption of the accreditation régime. The second suggestion was that indicators of the

quality of pathology services in Victoria could be compared with their equivalents in other States and Territories to determine whether the quality of pathology services in Victoria is superior to those services provided elsewhere in Australia. The third suggestion was that indirect indicators of the effectiveness of the accreditation system could be identified and assessed.

4.1.1 Measurement of improvements over time

Of the three mechanisms identified in the Discussion Paper for estimating the benefits of the legislation, it was argued that the first two are superior to the third in that they involve a direct measurement of the outcomes of the system rather than a reliance on indirect indicators. However, the Discussion Paper also explained that a number of difficulties arise in respect of their use.



If comparison of the performance of the pathology services industry over time did indicate clear improvements, these may be due to factors other than the introduction of accreditation. Additional evidence would be needed 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 process operated by the Commonwealth. The Discussion Paper suggested the likelihood of achieving this in practice would be minimal.

While a number of industry participants and others argued to the Review Panel that the quality of pathology services has, in general, improved over time, little direct evidence of such improvement was offered. Moreover, little argument was presented as to the reasons for the claimed improvements, beyond a general assertion they had been due to the conduct of the PSAB and the operation of the legislation. It was not within the scope of this review to conduct original research on the state of pathology practice and trends therein over time. Given this, and the above-mentioned lack of argument and evidence in the submissions, the Review Panel considered the view taken in the Discussion Paper had been borne out in practice. That is, it has not been possible to adduce strong direct evidence that the Act has had substantial benefits in improving the performance of the industry.

4.1.2 Comparative performance

The second mechanism suggested in the Discussion Paper was considered to 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 the performance of services in Victoria and in other States and Territories might be attributable to the accreditation process. A difficulty in undertaking a comparison of performance is that factors other than the operation of an accreditation system can influence industry performance, and the effect of these factors will be difficult to separate out. Any such comparative analysis would, for example, need to take account of the impact of the operation of the Office of the Health Services Commissioner (HSC), legislation such as the *Medical Practice Act 1994* and *Fair Trading Act 1999* and non-regulatory mechanisms such as common law provisions.

The question of whether the Victorian legislation provides significant material benefits to consumers, relative to other States and Territories, generated vigorous debate. While a number of those making submissions to the review (for example, the HSC, the Australian Association of Pathology Practices Inc., Eastern Health) considered there was no objective evidence that the Victorian accreditation system provides significant material benefits to consumers relative to other States and Territories, other commentators argued the contrary. The Australasian Association of Clinical Biochemists Inc., for instance, expressed the view that

The experience from unregulated laboratories in states other than Victoria clearly indicates the lack of adherence to basic quality principles and the reluctance to participate in external Quality Assurance and peer review activities. This is emphasized by the fact that nearly one half of all Medical Practice pathology services (Category G laboratories)(sic) in the Office Pathology Quality Assurance Programme provided by the RCPA/AACB Quality Assurance Programmes are from Victoria. This clearly demonstrates that in an unregulated environment, medical practice office laboratories do not participate in the simplest form of peer review or consistently participate in an external Quality Assurance programme.



Thus, the alleged effect of the legislation in improving pathology practice was considered to be due, in the main, to the fact that the Victorian legislation requires pathology laboratories to be involved in quality assurance programs. However, as noted above, similar provisions also apply to pathology services accredited under the Commonwealth régime. Through standards set by NPAAC the Commonwealth currently requires all laboratories to participate in external quality assurance programs covering all test methods performed in the laboratory and for which such programs are available (NPAAC, 1998). NPAAC recently reviewed this requirement and sought industry feedback on new draft Standards for Pathology Laboratories (<http://www.health.gov.au/npaac/pdf/pathlabs.pdf>). The draft standards not only retain the requirement for laboratories to participate in quality assurance programs, but impose a further requirement that laboratories be enrolled in such programs and perform to an acceptable standard. Further, in terms of pathology services accredited solely under the Victorian régime, a telephone survey conducted by the Review Panel found that most services stated that they would retain their involvement in quality assurance programs in the absence of legislation due to other commercial and professional imperatives.

4.1.3 Indirect indicators of performance

The third mechanism suggested in the Discussion Paper as a means of assessing the benefits of the Victorian legislation was the identification and assessment of indirect indicators of the effectiveness of the accreditation system itself. While the Discussion Paper acknowledged that indirect indicators of regulatory performance are generally less preferable than direct indicators, it also noted that these indicators formed the bulk of the data available to the Review Panel. The following discussion

presents the available indicators of the effectiveness of the accreditation system that have been obtained by the Review Panel following the release of the Discussion Paper and considers the performance of the legislation and the PSAB in this context. The discussion also draws conclusions on the likely impact of the accreditation system in practice, including comparisons of its impact *vis-à-vis* various alternative mechanisms. Those indicators that were presented in the Discussion Paper will not be reintroduced here.



Role of the PSAB in the accreditation system

Section 9 of the Act specifies that the functions of the PSAB are to:

- accredit pathology services;
- categorise each accredited service;
- recommend to the Minister proposals for regulations, the types of tests that may be conducted according to the category of accredited service, which tests should be prescribed as exempted or non-regulated; and
- supervise the maintenance of registers and records required to be kept under the Act.

These functions can be considered to be 'instrumental'. That is, they are required to be performed in order to give effect to the regulatory system created under the Act, but do not relate directly to the achievement of regulatory objectives.

Other functions the Act requires of the PSAB include:

- supervising the maintenance of standards;
- directing services to comply with standards; and
- suspending or canceling the accreditation of a pathology service;

The first two are related to achieving regulatory objectives, while the third can also be considered 'instrumental'.

According to submissions made by the PSAB, the Medical Scientists' Association of Victoria, the Australasian Association of Clinical Biochemists Inc., Alfred Pathology Service and the Australasian Association of Clinical Biochemists Inc.– Victorian Branch, there are a number of additional functions that the PSAB undertakes. These functions include:

- confirming the enrolment of services in external quality assurance programs;
- confirming the qualifications of the person in charge and the number of laboratories supervised by that person;
- overseeing inspections of Victorian pathology services undertaken by NATA and the RACGP;
- reminding NATA when inspections are due and instructing NATA to conduct follow-up inspections;
- following up on services' responses to inspection reports;
- investigating laboratories that offer unusual, non-validated tests;
- investigating complaints;
- providing educational assistance/advice to the industry; and
- representing Victoria on national advisory committees such as NPAAC.



A number of respondents stated that the PSAB has strong credibility within the pathology services industry. For instance, the Australasian Association of Clinical Biochemists Inc. stated in its submission that, "professional groups with specific knowledge of pathology hold the PSAB in high regard". The Association added that

Not only does the PSAB maintain oversight of the quality and overall activity of pathology services within Victoria, but it acts as an independent arbiter, advisor and technical educator for Government, individual pathology services and for the public. The PSAB is the only group which provides "local" expert knowledge and an independent overview of the technically complex discipline of pathology. The PSAB with an independent chairman and representation from pathologists, medical scientists and medical practice, has provided a focus without undue emphasis on the professional qualifications of any particular group or from those with a vested interest. ... The independence of the Board is a key factor in the overall accreditation process, as even self regulation by separate professional groups cannot provide the same consistency and scope of experience.

Moreover, the Association's Victorian Branch added that it "...strongly supports the current role of the PSAB in regulating and accrediting ALL categories of pathology service, whether Medicare rebateable or not" and added that the PSAB "...has helped many small Medical Practice Laboratories (Category 5) (*sic*) in aspects of internal and external quality assurance of pathology tests over many years".

Eastern Health's submission discussed the process of accreditation in Victoria and expressed the view that the Victorian régime effectively 'rubber-stamps' the Commonwealth's accreditation of laboratories. Eastern Health added that

...as an instrument to protect the public by ensuring that proper standards of practice are maintained, the [PSAB] does not contribute anything further than the Commonwealth accreditation regime i.e. the NATA/RCPA assessment process.

In its consideration of the role of the PSAB in the accreditation process, the Victorian Healthcare Association Ltd. felt that "...the PSAB as it currently stands requires reform to ensure that it operates efficiently and effectively" particularly in terms of the PSAB's role *vis-à-vis* the Commonwealth.

Finally, the Royal Australian College of General Practitioners Victoria expressed concern that the "...ability of the Board to act has been poor and no prosecution of, (let alone police interview), groups who regularly enter Victoria with portable cholesterol units in caravans, has occurred".

Role of the PSAB in handling complaints

Another role of the PSAB that was highlighted in some submissions was its function of handling complaints against pathology services. For example, the Victorian Healthcare Association Ltd. stated, "the Board is the only mechanism which has legislative teeth for dealing with complaints". Similarly, the Alfred Pathology Service stated that "a...role of the PSAB is as a recipient of complaints and as a body that reacts to complaints that are received. Currently there is no other mechanism how complaints in the pathology industry are dealt with".

The Discussion Paper noted that, notwithstanding the above views, the number of complaints handled by the PSAB is very low, totaling 22 over the entire course of its existence to date (Pathology Services Accreditation Legislation Review, 2001: 37). The Review Panel however has noted the contention of the PSAB that, as a tool for detecting substandard pathology, the complaints process is weak because consumers are not in a position to judge the quality of a test result let alone its interpretation. The Discussion Paper identified other possible explanations for the low number of complaints to the PSAB including the indirect relationship between the pathology service provider and the consumer and the low public profile of the PSAB.

A number of submissions took the view that the overall level of consumer complaints in relation to pathology services was low and could be expected to remain low. The Australasian Association of Clinical Biochemists Inc.– Victorian Branch argued "pathology is not a discipline in which there are a large number of complaints" and the Medical Scientists' Association of Victoria similarly stated "complaints are few, as one would expect given the general professionalism of the industry and the climate of regulation that exists".



These statements appear to reflect a misapprehension that the PSAB is the only body to which complaints regarding pathology services are made. Indeed, some submissions explicitly made this point. It is not, however, correct. As pointed out by the HSC, both the Office of the HSC and the Medical Practitioners' Board of Victoria also receive complaints in respect of pathology services. The Review Panel did not have data on the number of complaints dealt with by the Medical Practitioners' Board. However, the role of this body is restricted to the performance of pathology tests by registered medical practitioners, including pathologists.

Since the publication of the Discussion Paper, the Review Panel received a substantial data set from the Office of the HSC in relation to complaints handled in respect of pathology services. This data are detailed below. In general terms, however, they indicate that the HSC plays a fundamental role in the investigation and resolution of complaints regarding pathology services in Victoria, receiving and resolving many times more consumer complaints than the PSAB. In its submission, the PSAB contended that although it handles complaints, this is not the most important function that it undertakes and suggests the profile of the HSC in dealing with complaints is not surprising given its role in this regard and the imperative for the HSC to cultivate a prominent public profile to attract complaints. The PSAB also added that the HSC has more staff and resources and that the "...Board would be prepared to play a more active role with regard to complaints but it would require more resources to do so". In light of the comments made by the PSAB and the data provided by the HSC, it is appropriate to consider the role and powers of the HSC in more detail.



The data provided by the HSC also suggest the level of complaints about pathology services in Victoria is high, when considered in comparative terms. The Victorian complaints experience of 248 complaints over 12 years compares with a total of 22 complaints in five years in New Zealand. Twenty-two complaints were received in the ACT over the last five years, with none relating to a non-Commonwealth accredited service provider. Other State and Territory Health Services Commissioners also reported receiving relatively few complaints.


A high number of complaints may not necessarily represent a higher level of consumer dissatisfaction in Victoria than other jurisdictions. Rather, it may reflect the existence of an effective and high profile complaints mechanism, which is accessible by a wide range of consumers and therefore reflects a strength of the Victorian system. However, this limited comparative data must cast doubt on any suggestions that the Victorian legislation has led to a higher quality of industry practice.

Role of the Office of the Health Services Commissioner in complaints handling

The Discussion Paper explored the role of the Office of the HSC in relation to the redress of complaints regarding pathology services. Although the *Health Services (Conciliation and Review) Act 1988* does not expressly include pathology services in its definition of health services, the purview of the HSC does, in fact, extend to these services. This is demonstrated by the data, presented below, on the extent of the HSC's involvement in complaint handling in relation to pathology services since

1988. Table 4.1 contains the number and types of complaints received by the HSC for the period 1988 to June 2000 in relation to pathology services. The nature of the complaints received is described in Table 4.2.

Table 4.1: Complaints regarding pathology services: 1988 – 2000



Year	Type of complaint							Total
	Access	Administration	Communication	Cost	Rights	Treatment	Not specific	
1988	0	0	2	5	0	1	0	8
1989	0	2	4	24	3	4	0	37
1990	0	0	3	11	1	3	0	18
1991	0	4	4	22	3	5	0	38
1992	0	1	2	8	1	2	0	14
1993	0	0	2	4	1	3	0	10
1994	0	0	2	13	1	7	3	26
1995	1	3	3	20	1	6	0	34
1996	0	0	0	4	1	1	0	6
1997	1	4	0	3	1	8	0	17
1998	1	1	1	4	1	2	0	10
1999	1	2	2	2	1	2	0	10
2000	1	4	2	5	1	6	0	18
Total	5	21	27	126	16	50	3	248

Source: Office of the Health Services Commissioner, August 2001

Table 4.2:
Nature of complaints made regarding pathology services, 1988-2000

Access		Rights	
Delay in treatment	1	Access to records	4
No/inadequate service	2	Accuracy of records	1
Refused admission	1	Discrimination	1
Transfer unsuitable	1	No/insufficient consent	2
	5	Privacy/confidentiality	6
Administration		Unprofessional conduct	1
Management practices	6	Other	1
Advertising	1		16
Other	6	Treatment	
Public health standards	6	Inadequate diagnosis	5
Quackery/legality	2	Inadequate treatment	4
	21	Medication	1
Communication		Negligent treatment	5
Absence of caring	1	Other	3
Failure to consult	3	Rough treatment	4
Inconsiderate/undignified service	8	Unskillful/incompetent treatment	11
Poor attitude/discourtesy	3	Wrong diagnosis	14
Wrong/misleading information	12	Wrong treatment	3
	27		50
Cost		Not specified	3
Amount charged	54	Grand total	248
Billing practices	30		
Fraud	3		
Information on costs	15		
Other	19		
Over servicing/unnecessary treatment	4		
Public health insurance	1		
	126		



Source: Office of the Health Services Commissioner, August 2001

The Office of the HSC provides an accessible, inexpensive, timely and independent mechanism for the resolution of disputes between health service providers and users. This mechanism has been created with a view to improving the quality and standards of health services. Review of the above statistics indicates that consumers of pathology services have made substantial use of this mechanism. The total number of complaints received by the HSC in relation to pathology services exceeds that received by the PSAB by a factor of around ten to one (that is, 248 complaints received

by the Office of the HSC over 12 years versus 22 complaints received by the PSAB over 10 years). As noted in the Discussion Paper, a majority of the 22 complaints received by the PSAB have been made by other industry participants, rather than consumers. Thus, consumers have taken their complaints to the HSC rather than the PSAB by a ratio of more than 20 to one. In this context, it is notable that the submissions that argued that the incidence of complaints in the industry was low were received from industry participants. It appears that there may be a 'split' between industry participants, who are aware of the PSAB but have a low level of

awareness of the consumer complaints functions of the Office of the HSC, and consumers, who are generally unaware of the existence of the PSAB but make significant use of their rights to complain to the HSC.



According to the information provided to the Review Panel by the HSC, the complaints received by the HSC about pathology services are predominantly concerned with poor communication, costs and incorrect results. The HSC advised that quality improvements have occurred in pathology services as a result of conciliation and complaints resolution. These improvements have included:

- better procedures to ensure confidential handling of patient information;
- improvements in communication; and
- improved procedures for gaining informed consent, including informed financial consent, by providing better information to patients about the costs of pathology services.

The HSC also advised that, in the resolution of complaints about pathology services, the majority of complainants wanted to see systemic quality improvements as a result of their complaint. The overwhelming majority of complainants want to know what went wrong and why, and they want to make sure that the same thing does not happen again to someone else.

Further, the Health Services (Conciliation and Review) Act confers upon the HSC the ability to refer a complaint to a registration board or to a person or agency. Consequently, if the complaint warrants investigation by an expert in pathology, the HSC can refer the complaint to such an individual or to an organisation such as the PSAB, NATA, HIC or the Medical Practitioners' Board of Victoria (section 19 (7) of the Health Services (Conciliation and Review) Act).

Complaints handling – concluding remarks

As noted above, data available to the Review Panel since the publication of the Discussion Paper indicates that the low number of complaints received by the PSAB does not indicate a lack of consumer dissatisfaction with pathology services. Rather, consumers are either consciously choosing to take complaints to the HSC in preference to the PSAB or are unaware of the existence of the PSAB. In this context, the RACGP Victoria in its response to the RIS argued

...it is distressing (and it is perhaps indicative that there is very little need for the PSAB) that twenty two complaints were received, many of which were from competing organizations with respect to such things as advertising.



Whichever is the explanation for the paucity of consumer complaints brought to the PSAB, it is clear its contribution to the resolution of consumer dissatisfactions with pathology service providers has been minimal by comparison with the HSC. To the extent that the explanation for its limited involvement lies with consumer ignorance of the PSAB's existence, it is conceivable that steps could be taken to enhance its involvement in this area. Were consumers aware of the existence of the PSAB, it is possible they would take complaints to it in the first instance, given that it is specialised in the regulation of the pathology industry and the fact that the PSAB does appear to have a sufficient range of powers to deal with consumer complaints. Conversely, it may be that consumers prefer to take advantage of the HSC's experience and expertise in conciliated dispute resolution.

Even given a positive consumer response, increasing the role of the PSAB in complaint resolution would require a substantial marketing expenditure so that a far greater awareness of its existence was generated. Similarly, as acknowledged by the PSAB, a substantial increase in staffing and resources would be required to allow for an effective complaint resolution capacity. This is considered to be highly unlikely, given the small revenue base from which the PSAB currently operates and the fact that any increases in such expenditures would necessitate substantial increases in State accreditation fees. More importantly, the Review Panel heard no evidence of consumer dissatisfaction with the HSC's complaints resolution performance in this area. Hence, there may be no substantial gain from attempts to divert such complaints from the HSC to the PSAB.

5. Consideration of future options for the regulation of the Victorian pathology services industry



The Discussion Paper proposed five alternatives to the current Victorian pathology services legislation that could ensure the maintenance of high standards within the pathology industry. In presenting these options the Review Panel sought to gauge the views of the industry and the public about the future regulation of the pathology services industry in this State. In particular, the Review Panel wished to ascertain stakeholders' views on whether the continuation of the existing legislation, with its restrictions on competition as identified above, constituted the only means of assuring adequate control over the standard of pathology practice in Victoria or, whether other options less restrictive of competition could achieve this underlying objective of the Pathology Services Accreditation Act. As anticipated, the five options canvassed in the Discussion Paper generated substantial comment. The following sections discuss the main responses to the options included in the Discussion Paper and include the Review Panel's conclusions in relation to these arguments and the merits of each of the options discussed.

5.1 Options 1 and 2: Retention of a State-based accreditation system for all Victorian pathology services

Options 1 and 2 envisaged the retention of a State-based accreditation system for all Victorian pathology services. They differed in that, under option 2, the State accreditation authority would also become the agent of the Commonwealth in Victoria in respect of its accreditation requirements. Option 1 entailed the retention of Victoria's current statutory accreditation system, but would amend the Act to incorporate the key elements of the model framework that currently applies to the regulation of health practitioners generally in Victoria, following the implementation of post-NCP reforms throughout the majority of this sector. The Discussion Paper argued that option 1 would be the most appropriate reform if it were considered that:

- the potential for harm inherent in the conduct of pathology services is such that specific State-based regulation is necessary to protect the public;
- the absence of State-based 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 services 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;
- 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 terms of those services which are subject to dual accreditation (that is, Commonwealth and Victorian accreditation), the Victorian accreditation system adds value by affording patients and other users of pathology services a greater level of protection than that afforded by the operation of the Commonwealth system alone.

As noted above, the second option is similar to option 1, but would reduce duplication between the State and the Commonwealth accreditation systems by establishing the Victorian accreditation authority as an agent of the Commonwealth in this State. The Discussion Paper suggested this option would be appropriate if, in addition to those considerations listed under option 1, it were also 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 imposed on pathology services that are currently required to be accredited under both Commonwealth and Victorian schemes.



5.1.1 Views presented in submissions – option 1

The question of whether Victoria should retain a State-based accreditation system that operates in tandem with that of the Commonwealth provided the focus for the majority of submissions made to the Review Panel. The submissions received by the Review Panel were equally divided on the threshold question of whether separate Victorian legislation should be retained, with both supporters and opponents of the current Victorian legislation putting forward strongly held views.

Arguments in favour of option 1

Many of those arguing for the retention of a State-based accreditation system for all pathology services argued that, from a competition perspective, the current legislation does not impose restrictions but rather ensures that a level playing field exists through the establishment of common minimum standards. A secondary line of argument made by the Medical Scientists' Association of Victoria was that "...if the review does determine that the [Act] is restrictive, the [National Competition Council] acknowledges that it is possible that 'restrictions provide some benefit'". Consequently, the Medical Scientists' Association of Victoria argued the legislation neither restricts competition nor imposes a cost burden on the community. The Association added that the benefits provided by the legislation "...far outweigh the minor cost impositions on parties with a personal stake, such as pathology laboratories" and for this reason suggested that

although 'a restriction is guilty until proven innocent', with regard to the benefits outweighing the negative aspects of the restrictive practice, the existence of a regulation does not mean it is restrictive and thus the philosophy does not necessarily apply. If a regulation can show it is not restrictive, the onus of guilt or innocence returns to the accusers.

Others, more explicitly acknowledging the degree of restrictiveness of competition entailed in the Act, argued it was appropriate and acceptable, given the nature of the industry and the consumer protection issues involved. On this basis, the Australasian Association of Clinical Biochemists Inc. contended that

there are many regulations which the community accepts as providing a rational approach to the proper functioning and protection of society. Road traffic regulations and the regulations governing medical practice are obvious examples. Pathology as a highly specialised and technical discipline is no exception.



It was further argued that the protections and costs savings afforded to the community by the operation of the legislation significantly outweigh the costs attributed to the PSAB. Supporters of the current accreditation process argued that the system ensures all Victorian services participate in quality assurance activities and, as a result, high quality services are provided at very low cost to the Victorian Government. Supporters also suggested the scope and authority of the PSAB should be expanded (Australasian Association of Clinical Biochemists Inc. - Victorian Branch, Australasian Association of Clinical Biochemists Inc.).

The Australasian Association of Clinical Biochemists Inc. and the Association's Victorian Branch, rested their arguments in favour of the retention of the Act on two pillars:

- first, the standards serve to protect the community because

It is naive and inaccurate to assume that all the requestors of pathology services, either medical practitioners or individuals within the community, have the technical knowledge to judge the quality (precision, accuracy, specificity, reliability) of particular pathology results or the overall competence of the pathology provider (Australasian Association of Clinical Biochemists Inc.).

It was also suggested that “the consumers of pathology services (the patient, the public in general and most medical practitioners) do not have the technical knowledge or access to the specific data required to make such judgements”...[and]...“it is only through regulation that requires adherence to minimum standards that confidence can be assured” (Australasian Association of Clinical Biochemists Inc.).

- second, it was argued the Act provides an independent overview of the pathology industry, with the PSAB having the expertise to provide assistance and advice to government and individual pathology providers as required.

Moreover, the Australasian Association of Clinical Biochemists Inc. noted

Constitutionally, health is a State Government responsibility. The Commonwealth Government and its agencies such as the Health Insurance Commission (HIC) have minimal jurisdiction over pathology services. The only sanction that the Commonwealth can apply is the withdrawal of Medicare benefits. This may be a suitable incentive for mainstream pathology which relies on Medicare funding, but the public is also exposed to many providers who require a fee for service payment which is not rebatable by

Medicare. It is obviously in the vested 'best interest' of these services to operate in a non regulated environment, but in this circumstance, the community has no guarantee of minimum standards or quality testing. Outside of Victoria, non-Medicare rebateable pathology is unregulated. . . .

The Victorian Healthcare Association Ltd. added that “in other states, there is no mechanism for preventing entrepreneurial laboratories from providing pathology tests of spurious value and charging the unknowing patient exorbitant fees”. Furthermore, the Association contended that “the Victorian legislation provides the process by which poorly performing laboratories can be prevented from operating”, whereas the Commonwealth accreditation system relies upon the power of the HIC “to reduce the level of Medicare funding, with recourse to a very lengthy legal process, during which a laboratory may continue to operate...”.



Similarly, the Alfred Pathology Service argued

...there is a large number of laboratories that do not fall under the HIC legislation and that would not be accredited at all if the role of the PSAB was not filled. . . It is important to have those laboratories appropriately accredited to make sure that a sufficient standard is guaranteed. The consumer will be concerned about the accessibility and the price of pathology but is not in a situation where they can judge the quality of pathology.

The submission from the Alfred Pathology Service concluded that the best possible system would be a federal system of accreditation of all laboratories, but that, in the absence of such a body, other States and Territories should consider setting up similar bodies to the PSAB to accredit their local pathology testing. The Alfred Pathology Service also argued for improvements to the existing Act, including the implementation of consumer representation on the PSAB, and suggested that likely future health care trends, such as the adoption of United States-style Health Management Organisations, could increase the need for regulation of the pathology industry by reducing the effective choice able to be exercised by medical practitioners and patients.

Arguments against option 1

Those submissions that argued against option 1 largely focused on the extent of the current duplication between the State and Commonwealth accreditation systems and indicated that addressing this duplication should be a key priority. For instance, Peter MacCallum Cancer Institute argued, “...the major issue is the unnecessary duplication of the Commonwealth and State statutes, an arrangement that is unique to Victoria...[and, consequently]...[Peter MacCallum Cancer Institute is] against options 1 and 2 because they would perpetuate the ...duplication”. Similarly, Eastern Health stated that it was “...not aware of objective evidence of significant material benefits relative to other Australian States of the Victorian accreditation regime running parallel to the Commonwealth regime”. Eastern Health added, “pathology services are of significant interest to the public, justifying appropriate regulation. However, there does not appear to be a requirement for two (2) accreditation regimes with similar accreditation criteria and processes as currently exists”. Further, as indicated earlier, Eastern Health argued

The accreditation process of pathology laboratories in Victoria is a practice whereby laboratories are accredited by the Commonwealth regime with subsequent 'rubber-stamping' by the Victorian regime. There is no assessment of a pathology laboratory's performance, particularly with regard to quality issues, by the Victorian regime independent of the Commonwealth regime. Therefore as an instrument to protect the public by ensuring that proper standards of practice are maintained, the [PSAB] does not contribute anything further than the Commonwealth accreditation regime. ...



The same submission noted that a range of other means of ensuring good practice existed (including the HIC regulations, Commonwealth accreditation regime, civil liability at common law, consumer protection laws, OH&S laws and government instruments, such as the HSC) and were "in practice more substantive and transparent". Moreover, Eastern Health argued that the current legislation is outdated in that there have been marked changes in communications technology permitting remote access to many laboratory processes. These changes have resulted in a need to reassess the type of skills required by persons conducting pathology testing and the need for 'direct supervision' so that the improvements in technology may be harnessed to realise significant efficiency gains without an adverse impact on quality. This issue was raised earlier in the discussion.

5.1.2 Views presented in submissions – option 2

As noted, option 2 differed from option 1 solely in proposing that the Victorian accreditation authority would act as the agent of the Commonwealth in regard to its accreditation system in Victoria. The purpose of this proposal was to reduce duplication and overlap at the administrative level by ensuring that pathology services in Victoria would need to deal with only one accreditation authority, despite the continued existence of two accreditation systems.

Arguments in favour of option 2

Arguing in favour of option 2, the Victorian Healthcare Association Ltd. stated

A system of state level regulation is regarded as key to upholding quality and thus public safety in pathology services in Victoria. The [PSAB] provides an invaluable safety net, filling the gaps which the Commonwealth regulatory processes do not cover.

However, as noted earlier, the Victorian Healthcare Association Ltd. indicated that the PSAB requires reform to ensure it operates efficiently and effectively. Thus, for the Victorian Healthcare Association Ltd., option 2 is preferred. Option 2 addresses duplication and clarifies the issue of the hierarchy of the two accreditation systems, while ensuring the continued application of PSAB regulations across Victoria, and that option 2 would represent "...the most appropriate and effective means of ensuring high quality practice in the industry".

Network Pathology, Austin & Repatriation Medical Centre argued for a combination of options 2 and 3, so that a State organization, acting through, or independently of, the Commonwealth would have jurisdiction over laboratories in Victoria not otherwise accredited.

5.1.3 Options 1 and 2 - conclusions of the Review Panel

The Review Panel has not been convinced that the retention of State-specific legislation applying to all pathology services, as implied by options 1 and 2, is justified. In terms of the tests set out in the Discussion Paper (pp 51-52) for the acceptance of these options, the Review Panel has accepted that there is a substantial risk of harm to patients if pathology services are of poor quality, but has not accepted that the absence of State legislation would substantially increase this risk of harm.

In the first instance, the Review Panel has formed the view that there is little potential for the Victorian accreditation regime to add substantial value in relation to the great majority of pathology services that are also accredited under Commonwealth arrangements. This conclusion rests in large part on the deliberate alignment of the two accreditation systems, undertaken over a period, in order to ensure minimal effective duplication. While arguments have been made as to the theoretical benefits of specific enforcement powers possessed by the PSAB and its powers to review NATA inspectors' reports, the Review Panel has formed the view that convincing arguments have not been presented to indicate these powers have had a significant impact in practice. Further, the Review Panel believes there is a substantial likelihood this position could change in the future, given a range of practical considerations, including the resource limitations that would necessarily continue to constrain any actions by the PSAB. Also significant has been the Review Panel's observation that the PSAB had not functioned as the main vehicle for the resolution of the substantial number of consumer complaints that have arisen in respect of the pathology industry.



Given this conclusion, the case for the Victorian legislation having substantial harm-reduction effects would need to rest, in essence, on its role in relation to pathology services not accredited by the Commonwealth. However, the information received since the publication of the Discussion Paper showed only a very small proportion of pathology services performed in Victoria fall outside the ambit of the Commonwealth's accreditation system. In this context, the Review Panel has noted that many of the submissions that argued for the retention of State-specific legislation did so on the basis of an apparent misapprehension as to the size of this subset of pathology services.

The Review Panel has also taken the view that the nature of the services provided by these non-Commonwealth accredited service providers, as well as the context in which they operate, is such that the risks likely to be associated with the removal of State accreditation are small. In this context, the Review Panel has noted that two thirds of this group (twelve of nineteen) provide only screening tests against a narrow range of indicators. Where such tests indicate grounds for concern and possible health interventions, they will invariably be confirmed by further and more sophisticated testing. Thus, the risks in this regard are low. There is some possibility that 'false negatives' arising in this context could have negative health impacts, although the Review Panel believes the incidence of such problems is likely to be relatively low given the nature of the testing technologies under consideration. Moreover, the Review Panel has been persuaded that the current restrictions are likely to be reducing substantially the availability of such testing. Hence, any increased risks in the above

respect must be balanced against likely benefits in relation to increased access to testing and, hence, earlier detection of health problems.

In relation to the remaining seven pathology services, which provide a broader and more sophisticated range of tests, the Review Panel has noted that five are located within the public sector, of which three are attached to major teaching hospitals and one is a part of a university. The Review Panel has formed the view that substantial incentives are likely to exist toward the maintenance of high quality testing among this group, even in the absence of a Victorian accreditation process. The removal of such a process would, therefore, not be likely to substantially increase risks to patients. Similarly, the two private sector providers, as providers of specialised services, face clear commercial incentives to maintain quality standards.



The Review Panel has concluded, therefore, that the retention of State-based accreditation for all pathology services cannot be justified on the basis of the prevention of increased harm to consumers. In this context, it has noted the existence of a range of other mechanisms that would continue to have an impact in maintaining quality standards in the industry in the absence of a Victorian accreditation system. As enumerated in the Discussion Paper, these include the common law, State and Commonwealth consumer protection laws, market forces, contractual conditions imposed by payers, industry standards and insurance industry requirements. They also include the jurisdiction of the Victorian Office of the Health Services Commissioner that, as noted above, has functioned to date as the main complaints resolution body for the Victorian pathology industry, and can be expected to continue to do so.

5.2 Option 3: Retention of a residual 'safety net' regulatory system

The third option presented in the Discussion Paper was that Victoria could retain a residual 'safety net' regulatory system under which State-based legislation requiring accreditation would capture only those pathology services that are either ineligible to seek Commonwealth accreditation or are eligible for Medicare reimbursement, and thus Commonwealth accreditation, but choose not to do so. Under option 3, only those services not captured under the Commonwealth's accreditation system would be regulated by the State. It was suggested this option would be an appropriate response if it were considered that:

- there is a very real and direct risk of harm to the public associated with the operation of services that are not accredited under the Commonwealth 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;
- the key fault of the existing arrangement is the duplication which imposes on pathology services that are currently required to be accredited under both Commonwealth and Victorian schemes; and
- the cost involved in maintaining the infrastructure necessary to carry out State-based regulation for a small number of pathology services is viable and is outweighed by the benefits of regulation.

5.2.1 Comments raised in the submissions

Several submissions addressed the question of whether option 3 would provide an appropriate mechanism for the regulation of those services not captured under the Commonwealth's accreditation régime. A number of these expressed the view that the current Victorian system of accreditation for those services not captured under the Commonwealth's régime was unwieldy, unnecessary and cost-prohibitive. However, the majority of these respondents believed the State should maintain a role in the regulation of non-Medicare remunerated services. The Royal Australian College of General Practitioners Victoria for instance, envisaged a role for a regulatory authority, such as a smaller version of the PSAB, to cover non-Medicare remunerated services

...in order to control rogue laboratories performing tests of dubious scientific value...[and]...to ensure that new, medically proven tests which as yet have not been granted a Medicare rebate under the Schedule but which may well be scientifically valid...[be subject to] quality control.



While holding a similar view, the HSC did not propose that a specific regulatory authority be established to undertake this function but instead suggested that the State look to regulating non-Medicare remunerated services in an "...appropriate way". To this end, the HSC proposed that the Review Panel consider an amalgam of options 3 and 4 (negative licensing).

In describing option 3, the Discussion Paper suggested that a substantial disadvantage likely to be attached to option 3 was the cost involved in maintaining the infrastructure necessary to carry out the State regulatory function for a small number of pathology services. Only two respondents commented on the issue of costs in relation to this option and these comments were diametrically opposed. Peter MacCallum Cancer Institute believed that the cost of accreditation under this option should be borne by the laboratories and would not be prohibitive. The Victorian Health Care Association Ltd., however, maintained high costs would be imposed on a small number of laboratories.

5.2.2 Option 3 - conclusions of the Review Panel

The Discussion Paper argued that the implementation of option 3 would only be appropriate if three key factors were satisfied, namely, that:

- (i) there is a very real and direct risk of harm to the public associated with the operation of services that are not accredited under the Commonwealth system;
- (ii) 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
- (iii) the key fault of the existing arrangement is the duplication which imposes on pathology services that are currently required to be accredited under both Commonwealth and Victorian schemes.

A further consideration, as noted above, is that the cost involved in maintaining the infrastructure necessary to carry out State-based regulation for a small number of pathology services would need to be viable and be outweighed by the benefits of regulation.

The Review Panel does not believe these conditions have been met. It was clear to the Review Panel that the duplication involved in the current accreditation system constitutes a key fault of the system

and the major justification for the retention of a State-based accreditation system would therefore need to be established in terms of its impact on the group of services currently accredited only under a State scheme. However, the above discussion (see options 1 and 2) of the numbers of services involved and the likely risks to the public posed by this group, as well as the alternative quality control mechanisms already in place, has strongly suggested to the Review Panel that such risks are low. Moreover, the ability of the current legislation to ameliorate such risks was also considered to be limited and unlikely to be sufficient to justify the costs (both monetary and non-monetary) such a scheme would impose.



Further, if a State-based accreditation system, administered by a regulatory authority such as the PSAB – even a smaller version – were to be established, Government policy requires that such an authority would need to be self-funding. Policy in this regard reflects the economic efficiency principle that the full costs associated with the provision of a product or service should be reflected in its pricing if resource allocation distortions are to be avoided.

On the basis of the number of services currently accredited solely under the Victorian scheme, accreditation costs would be likely to be substantial. The Discussion Paper suggested that costs could be in the order of \$2,500 to \$3,000 per pathology service. However, these estimates were based on an assumption of a larger number of services being subject to the scheme than that which the Review Panel subsequently knew to be the case. Given that option 3 effectively supposes the establishment of an accreditation scheme to cover nineteen pathology services, it is likely these fees would be higher still. Thus, option 3 would imply a very substantial increase – probably more than tenfold – on the current fees.

For the majority of non-Commonwealth accredited services, such a cost would be prohibitive and might even create a perverse incentive to avoid accreditation. On this basis, the Review Panel does not believe the cost involved in maintaining an infrastructure necessary to carry out State-based regulation for a small number of pathology services is likely to be either viable or outweighed by the benefits of regulation. Consequently, the Review Panel has not recommend the implementation of a residual ‘safety net’ regulatory system requiring accreditation for those services not accredited under the Commonwealth’s system.

5.3 Option 4: Negative licensing

The fourth option presented in the Discussion Paper was termed ‘negative licensing’. Under negative licensing, legislation provides a mechanism for a competent authority such as a Government Department, a statutory authority or tribunal to disqualify a person who has been proven to be unfit to engage in a field of activity or to carry on a business from doing so. Alternatively, conditions can be imposed on the conduct of a business to protect the public. While this form of regulation has few known statutory precedents in Victoria, it has the potential to be a cost effective means of protecting the public by ensuring action can be taken to remove from the industry those who have proven by their behaviour to be unfit to conduct or be involved in the conduct of a pathology service. The Discussion Paper argued that negative licensing could be an appropriate mechanism if:



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

5.3.1 Comments raised in the submissions

All of the submissions that commented on option 4 expressed reservations about the appropriateness of a negative licensing system in terms of public safety. In short, respondents were concerned that the mechanism places too much reliance on industry self-regulation, it is a schema without known statutory precedents in Victoria and, in the event that action is warranted, authorities only respond after patients are put at risk.

5.3.3 Option 4 - conclusions of the Review Panel

The Review Panel has acknowledged that negative licensing is a fairly novel approach to regulation and is untested, at least in Victoria, in the area of public health. The Review Panel also acknowledged that it is a reactive means of dealing with the problems of sub-standard service provision and quality. Negative licensing 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. However, as indicated in the Discussion Paper and raised again in this Final Report, the Review Panel was interested in exploring whether a combination of regulatory and non-regulatory mechanisms could provide an alternative to the current regulatory régime.

Relying on a negative licensing scheme alone to regulate the pathology industry may indeed be inappropriate. However, any such scheme would not be operating in isolation, but rather would exist in the context of a comprehensive Commonwealth accreditation régime and a broader system of

regulatory and non-regulatory controls. Moreover, while the Review Panel has accepted there is always the potential for risks to the public to emerge from the conduct of pathology testing, it was not convinced the risks associated with non-Medicare remunerated services are so high to warrant a State-based accreditation schema, as explained above. On this basis, it is arguable that negative licensing may provide an additional tool by which the pathology services industry could be regulated. That is, a negative licensing scheme could be considered as a possible adjunct to the suite of regulatory and non-regulatory controls on pathology services that would continue to exist in Victoria in the absence of a State accreditation régime.



However, further consideration of this option has led the Review Panel to form the view that it is not likely to be appropriate in the current context. A key concern has been that a negative licensing scheme necessarily requires a decision-making body to determine when the sanction of negative licensing will be imposed, as well as a secretariat function to receive complaints and undertake monitoring and investigation activities. In both cases, a level of specific expertise would be required in order to ensure appropriate decision-making. A further consideration would be the need to ensure adequate appeal mechanisms were available.

The Review Panel was unable to identify appropriate arrangements to allow these functions to be exercised. Such functions would, for example, be inconsistent with the Office of the HSC's general role as a means of complaint resolution. It would also be inappropriate to consider conferring such a function on other professional regulatory boards operating within the health context. This leaves the theoretical option of creating a specific board for this purpose. However, given the low number of refused accreditations in the pathology industry in the past, it seems clear that the size of this task would be far too small to justify the existence of a dedicated board and secretariat function. Moreover, such an arrangement would be in many ways similar to the current model of a PSAB, supported by a dedicated Registrar. The difficulties inherent in such a model have been discussed elsewhere in this Final Report.

Thus, the Review Panel came to the view that a negative licensing scheme is not likely to be practicable at the present time. It may, however, merit further consideration in the future should the appropriate circumstances arise. Further research on other experiences with this regulatory model in the health context may be appropriate in the interim.

5.4 Option 5: Repeal Act and rely on existing regulatory and non-regulatory mechanisms

The fifth option presented in the Discussion Paper proposed the repeal of the Victorian legislation. The achievement of appropriate levels of quality assurance and consumer protection, including redress of complaints, would then rely on a combination of the Commonwealth accreditation scheme and the range of other existing regulatory and non-regulatory mechanisms. These mechanisms include non-statutory based 'accreditation' or 'quality assurance' mechanisms that are imposed on services

by contractual arrangements (including insurance arrangements) or voluntarily undertaken by services as part of a self-regulation process, and the requirements imposed by the *Health Act 1958* (Vic) and therapeutic goods legislation (Commonwealth and Victorian). They also include mechanisms such as the common law and the Office of the HSC.

The implementation of this option would bring Victoria into line with all other States and Territories, none of which has ever implemented State-based pathology services accreditation legislation. The Discussion Paper argued that this option would be appropriate if it were considered that:

- the risks associated with Victorian pathology services were similar to those in other jurisdictions;
- the existing standard of practice in other jurisdictions, which do not have their own accreditation regimes, is generally acceptable;
- there is little concrete evidence that the current Victorian accreditation regime has provided substantive benefits to consumers of pathology services; and
- the alternative means of ensuring high levels of practice in pathology services are adequate.



5.4.1 Comments raised in the submissions

Submissions were evenly divided in their views of this option. Many of those opposed to Option 5 argued that it would lead to a reduction in quality standards. For example, the Australasian Association of Clinical Biochemists Inc. – Victorian Branch argued that “there would be no major reduction in costs in repealing or scaling down the PSAB, only a major reduction in the standard of some Victorian pathology services”. Similarly, Network Pathology, Austin & Repatriation Medical Centre argued, “...(Option 5) would not address the issues of concern and potentially dangerously expose the public to unscrupulous practice”.

Other arguments were based on a more generalised expression of a view that accreditation and monitoring were required. The Medical Scientists’ Association of Victoria argued that “the Victorian Government should not consider removing legislation that performs the monitoring process at a time when there is increased pressure to improve quality outcomes and the overall quality of pathology laboratories”. The Peter MacCallum Cancer Institute stated that it did not favour Option 5, as “...there is a need to accredit laboratories performing pathology services that are not covered by the Commonwealth scheme”.

By contrast, many of those in favour of Option 5 emphasised, in particular, the duplication inherent in the current arrangements. RACGP Victoria argued that

...the Victorian Act is not consistent with the principle of minimum necessary regulation and the presumption against regulation...there is not a demonstrated problem with Medicare rebated testing and... the potential problems of other groups acting in an unregulated fashion and performing tests of dubious scientific validity and accuracy (while accepting that a potential harm has been identified) is relatively small.

In particular, RACGP Victoria noted that it should

... strongly oppose the continued involvement of the PSABV with respect to tests which are Medicare rebatable (more precisely Medicare rebated) as these tests are either generally (i) of great simplicity ...and do not require laboratory accreditation or (ii) more complex and require not only registration of the GP as an Approved Pathology Provider ...and of their laboratory as an Approved Pathology Authority...by the H.I.C. but also inspection by an agency approved by the H.I.C....There is an obvious duplication and a significant cost burden by also requiring PSABV accreditation which uses the same reports from the same inspection agencies for no additional benefit.



In addition, as raised earlier, RACGP Victoria noted that the ability of the PSAB to act has been poor and no prosecutions have occurred. It drew attention to the fact that the PSAB has dealt with only 22 complaints and argued that these complaints “...could have just as easily been referred to the Commonwealth as would most likely occur in other States”. Moreover, RACGP Victoria added that “the additional financial and regulatory burdens are clearly not justifiable and one would doubt that the current legislation has resulted in extra protection to patients”. RACGP Victoria’s submission concluded that it should “...support option 5 – [as] it would be prudent to argue that this is a role for the Commonwealth”.

The Australian Association of Pathology Practices Inc. stated

...we do find it anomalous that Victoria is the only state that has its own Pathology Services Accreditation Board... With respect to medical testing underwritten by Medicare and safeguarded by Commonwealth legislation and regulation including NATA/RCPA accreditation, the PSAB appears to be superfluous. There is no evidence that the citizens of other states suffer any disadvantage or risk in not having a similar local authority.

Moreover, the Association claimed that its impression is that

...most of the activities of the PSAB relate to the accreditation of laboratories for Medicare eligibility and consequently is an administrative and bureaucratic overhead not found in any other state. The same bodies recognised by membership of the Victorian board are represented on NPAAC and assert the same influence over standards and processes as they do in Victoria.

Professor Stephen Duckett, Dean, Faculty of Health Sciences, La Trobe University, joined Eastern Health in also supporting Option 5 arguing that the risks associated with pathology services in Victoria are similar to those in other States and Territories and the existing standard of practice in other States and Territories is generally acceptable. Eastern Health added that there is little objective evidence that the current accreditation régime provides substantive benefits to consumers and it considered the alternative means of ensuring high levels of practice in pathology services, such as the Commonwealth régime of controls and existing non-regulatory mechanisms, to be adequate. Moreover, Eastern Health argued the formal and non-formal regulatory mechanisms should, where possible, be uniform across all States and Territories.

Mayne Health also argued in favour of adopting an approach consistent with that used elsewhere in Australia, stating that

given that existing Commonwealth legislation safeguards the provision of cost efficient, high quality pathology services for doctors and their patients, it has not been considered necessary in any other State or Territory in Australia to create a statutory accreditation scheme like the [PSAB].

In addition, Mayne Health asserted that

to provide services in Victoria under Medicare, Mayne Health must seek approval from the [HIC] and [NATA]. Our impression is that most of the PSAB's activities centre on pathology services that seek eligibility for Medicare rebates... This duplication is time consuming, adds to the cost of undertaking pathology services in Victoria and provides no demonstrable positive effect towards the provisions of high quality clinical outcomes.



Another issue raised by Mayne Health related to the relative levels of expertise available to the regulators under the Victorian and Commonwealth systems. It argued

...[NPAAC], which advises the Commonwealth, State and Territory Ministers on matters relating to the accreditation of pathology laboratories, has a broader membership than the PSAB. The NPAAC brings together expertise from around the country to ensure it is appropriately representative and contains skilled people to professionally oversee the national accreditation scheme. Mayne Health therefore believes that Victorians are well served by the NPAAC and, as a consequence, there is no need for extra representation in the form of the PSAB.

The HSC was also broadly supportive of option 5, although she was particularly concerned to ensure adequate alternative means of ensuring quality were in place. The HSC stated “it appears to the HSC that there is now duplication and unnecessary regulation” and on this basis recommended that “...Commonwealth accredited services not be accredited by Victoria but that those not covered by the Commonwealth processes should continue to be regulated in Victoria in a more appropriate way”. Moreover, the HSC added, “abandonment of Victorian legislation is dependent upon the Commonwealth having all the necessary standards in place. I would also want aggrieved consumers in all states and territories to have access to the state based HSC or complaints commissioner as is the case in Victoria”.

The HSC’s proposals were based on the view that

under competition policy, competition prevails unless there are over-riding issues of public health and safety. I have no evidence to support an argument that Victorian pathology services are better than anywhere else in Australia. Indeed, it would appear that the Victorian Health Services Commissioner receives more complaints [regarding pathology services] than in other states and territories. This may be for a number of reasons.

5.4.2 Option 5 - conclusions of the Review Panel

The Review Panel has concluded that option 5 constitutes its preferred approach to the future regulation of the pathology services industry. This conclusion has been based primarily on the following considerations:

- The existing legislation is likely to have had substantial negative impacts on the supply of screening services in particular and, hence, on the availability of these services to consumers, with probable negative outcomes on public health;
- That the legislation, insofar as it regulates pathology services also accredited under Commonwealth arrangements, implies a very considerable degree of duplication and thus causes additional financial and administrative costs;
- That the legislation does not appear to have been effective in substantially improving the quality of pathology services supplied in Victoria;
- That a range of alternative mechanisms exist that are capable of substantially meeting the necessary quality assurance requirements in relation to the protection of public health; and
- That, to the extent that existing mechanisms are inadequate, they can be supplemented by additional controls that are less restrictive than the existing legislation.



Supply of Screening Services

The Review Panel was persuaded that the onerousness of the existing accreditation requirements was such as to act as a substantial disincentive to a range of bodies that might otherwise wish to supply screening services and, as a result, the supply of such services was likely to increase significantly in the absence of the accreditation requirements. Strong evidence to the Review Panel suggested the major effect of the limited availability of convenient health screening services would be to reduce the amount of screening activity undertaken and this is likely to have had substantial negative impacts on preventive health care strategies and achievements. To this extent, the Victorian community, through the removal of the Victorian accreditation requirements, may obtain substantial health benefits as they apply to this sector. Offsetting risks to health are considered to be small, as explained below.

Duplication of accreditation requirements

It was common ground between all parties that there was substantial duplication between the State and Commonwealth accreditation arrangements. From the point of view of the PSAB, this represented a conscious and quite appropriate attempt to harmonise regulatory arrangements between the two jurisdictions in order to minimise inconsistencies and additional costs to the majority of Victorian pathology service providers accredited in both jurisdictions. However, while this strategy has been successful in minimising the costs of the dual accreditation scheme, it has also substantially reduced the scope for arguing that the additional accreditation requirement at the State level provides unique

benefits to the consumer. In any event, these arguments were generally based on the ability of the PSAB to exercise closer control over pathology services that were not meeting performance requirements, both through the range of expertise represented on it and its access to a range of sanctions, including cancellation of accreditation. As noted in the Discussion Paper and in this Final Report, however, it is clear that these powers have been little used in practice.

The Review Panel has formed the view that the costs imposed by the duplication of accreditation requirements are relatively small for most pathology service providers. However, it also formed the view that the offsetting benefits arising are even smaller. Consequently, given the principles of good regulation – including that of minimum necessary regulation and the need for the benefits of a regulation to justify its costs – the Review Panel has concluded that this duplication should not continue.



Lack of effectiveness of the legislation

It is clear that judgments as to the effectiveness of the Victorian legislation are dependent upon the context in which they are made – that is, whether the legislation is considered in the context of the ongoing existence of the Commonwealth accreditation arrangements or not. Given that the Commonwealth arrangements will continue in the foreseeable future, it is apparent that the bulk of the industry will continue to be subject to the same substantive requirements whether or not the Victorian legislation is retained. Arguments as to the effectiveness of the Victorian Act must therefore be based on the marginal impact of the PSAB's role in relation to the review of NATA inspectors' reports and issue of instructions as to changes required. Evidence to the Review Panel suggested that the size of the impact of this function was small.

The effectiveness of the legislation in respect of the small non-Commonwealth accredited sector is potentially larger, since the Victorian legislation represents the only vehicle by which the raft of quality related requirements underpinning accreditation is imposed. However, the Review Panel is of the belief that the question of effectiveness must be considered in the context of the risks imposed to consumers from practice in these areas and the alternative mechanisms available that would operate to assure quality. The following discusses these issues in relation to each of the categories of non-Commonwealth accredited pathology services identified.

Screening services provide initial, indicative testing only, in relation to chronic disease. Evidence to the Review Panel clearly indicated that, in the event that screening results were possibly of concern, advice would invariably be given that a full test should be sought, following consultation with a medical practitioner. Moreover, the level of sophistication of these tests is relatively low, as they are largely automated. Thus, the likelihood of error was also considered to be relatively low. Taking these factors together, the Review Panel has formed the view that the risk to the public posed by such services is unlikely to be sufficient to justify the accreditation requirement, and that the application of the legislation to these services is unlikely to be effective in substantially promoting consumer protection.

Public sector facilities are, by definition, susceptible to controls of various kinds being imposed, where required, by Government. In particular, Government can, through its role as ‘purchaser’ of public health services, require appropriate quality controls as a condition of its contracts with these facilities. Moreover, public facilities, by definition, are not subject to the same profit making incentives that might be considered to lead to pressures to compromise quality among private providers. In addition, the outputs of these facilities are, in general, inputs to the provision of other public sector services, usually by parts of the same organisation. Thus, there are strong incentives to maintain high quality, from the point of view of overall cost minimisation. In this context, the potential benefit of the Victorian accreditation system is also considered nugatory and unlikely to be justified in terms of its costs.



Private sector facilities. As noted above, amongst non-Commonwealth accredited services these facilities number only four, two of which provide services almost exclusively under contract to large employers. In this context, it is considered likely there are strong market incentives for strong performance. Indeed, evidence to the Review Panel from one service indicated it was common practice for various quality assurance requirements, and verification mechanisms, to form part of the contractual arrangements, and for these requirements to frequently exceed those required under legislation.

Given the above, the Review Panel has concluded that the potential risks to the public arising from those pathology services solely accredited in Victoria are very small, and the impact of the Act in protecting the public in relation to these services appears to be minimal. Conversely, there may be grounds for believing the existence of the Act has had negative effects in reducing the availability of some tests. In terms of principles of good regulation, it does not appear that the regulatory issue passes the threshold test justifying Government intervention.

Availability of alternative mechanisms

The preceding sections of this Final Report have listed a range of alternative mechanisms that would continue to contribute to the maintenance of quality standards in the pathology industry. The Review Panel noted, in particular, that the Commonwealth accreditation system would continue to be applicable to all but nineteen of the existing pathology services. Moreover, when the likely throughput of these services is considered, as well as the nature of the tests conducted by most, it is clear that the vast bulk of pathology services would continue to be subject to equivalent alternative accreditation arrangements in the absence of the Victorian legislation and those that would not, for the most part, would be operating in relatively low risk areas of the market.

The Review Panel noted the role of the Office of the HSC. It is clear the Office of the HSC has, to date, functioned as the primary mechanism for the investigation and conciliation of consumer complaints in relation to pathology services, rather than the PSAB. Moreover, it is clear consumers are generally satisfied with the role of the HSC in resolving such complaints. Further to its role in complaints handling, the HSC has a number of other powers conferred to it by the Health Services

(Conciliation and Review) Act. These include:

- the ability to take evidence;
- undertake formal investigations, at the request of either the Minister for Health, either House of Parliament or any committee of either or both Houses of Parliament, of specific or systemic issues;
- table reports in Parliament;
- provide policy advice to the Minister for Health;
- participate in Ministerial advisory committees; and
- provide reports to the Minister and the Department of Human Services.

In terms of the latter, through its Annual Report, the Office of the HSC provides an analysis of complaints received, while quarterly reports provided to the Minister for Health and the Department of Human Services indicate complaints trends.



This alternative mechanism will clearly continue to be available to consumers in the absence of the Pathology Services Accreditation Act. In this context, the Review Panel has noted there would be little effective change either to the accreditation requirements applicable to most pathology services or to the means of redress exercised by consumers in the event of a complaint.

These alternative mechanisms, along with other relevant considerations such as market forces, contractual arrangements, the common law and general consumer protection legislation should provide a high level of continued confidence in the quality of pathology services in the event the Victorian Act were repealed.

Supplementation of existing controls with additional requirements

The Review Panel has formed the view that a number of additional steps should be taken to ensure a high level of public confidence in the quality of pathology services is maintained, in the event the Government accepts its recommendation that the Pathology Services Accreditation Act be repealed. First, the Department of Human Services should take a pro-active role in ensuring appropriate standards are required of all pathology services providers with which it has dealings. By reviewing all funding agreements, memoranda of understanding and other such arrangements, it would be able to ensure all such pathology services were required to comply with all relevant NPAAC standards, were regularly inspected by NATA and were enrolled and participating in appropriate quality assurance programs.

Second, the Minister for Health should write to his federal counterpart requesting similar arrangements be put in place in relation to all pathology services in respect of which Commonwealth funding was being provided, either directly or indirectly.

Third, the HSC should be formally requested to advise the Minister for Health in the event of concerns about the pattern, number of types of complaints being received about pathology services in the course of its complaints mediation role. Where such advice was received, the Minister should consider appointing an *ad hoc* expert advisory committee to investigate these concerns and advise appropriate action.

Fourth, the *Health Act 1958* should be amended to provide reserve powers for the Chief Health Officer. These powers could include the ability to undertake an investigation or enquiry in the event that the Minister for Health or the Department of Human Services is advised by the HSC, the HIC, CDH&A (including NPAAC), NATA or members of the pathology services industry of a laboratory that is operating at a sub-standard level. These powers should also include the ability for the Chief Health Officer to direct laboratories to notify patients and their medical practitioners in the event that the performance of a laboratory has been found to be sub-standard and, as a result, there is concern for public health.



The Review Panel has formed the view that these measures, considered in conjunction with the existing mechanisms for ensuring quality, discussed above, would be adequate to ensure that an appropriate level of quality was maintained by pathology service providers in Victoria, while being less restrictive and less costly than the existing legislative arrangements. Table 5.1 broadly summarises current legislative and non-legislative arrangements supporting the provision of quality pathology services and the measures proposed by the Review Panel that, in the absence of Pathology Services Accreditation legislation, will continue to support such provision.

Table 5.1 Summary of current and proposed arrangements supporting quality pathology service provision

Current PSAB arrangements supporting quality service provision	Other current arrangements supporting quality service provision	Proposed arrangements to support quality service provision
Accreditation functions – Medicare remunerated services	<ul style="list-style-type: none"> • Commonwealth accreditation arrangements • Evidence and legal accountability requirements • Contractual requirements for participation in quality assurance activities and standards maintenance • Public liability insurance requirements • Professional indemnity requirements • Office of the Health Services Commissioner • Requirements of the Fair Trading legislation • OH&S legislative requirements 	<ul style="list-style-type: none"> • Commonwealth accreditation arrangements • Evidence and legal accountability requirements • Contractual requirements for participation in quality assurance activities and standards maintenance • Public liability insurance requirements • Professional indemnity requirements • Office of the Health Services Commissioner • Requirements of the Fair Trading legislation • OH&S legislative requirements • Reserve powers of the Chief Health Officer under the Health Act 1958
Accreditation functions – non-Medicare remunerated services		
'In-house' screening services providing employee health screening	<ul style="list-style-type: none"> • Evidence and legal accountability requirements • Contractual requirements for participation in quality assurance activities and standards maintenance • Public liability insurance requirements • Professional indemnity requirements • Office of the Health Services Commissioner • OH&S legislative requirements • Requirements of the Fair Trading legislation 	<ul style="list-style-type: none"> • Evidence and legal accountability requirements • Contractual requirements for participation in quality assurance activities and standards maintenance • Public liability insurance requirements • Professional indemnity requirements • Office of the Health Services Commissioner • OH&S legislative requirements • Requirements of the Fair Trading legislation • Reserve powers of the Chief Health Officer under the Health Act 1958
Screening services for the general public conducted by partially or fully State-funded services, reference laboratories, research laboratories, public hospitals and Community Health Centres	<ul style="list-style-type: none"> • Evidence and legal accountability requirements • Contractual requirements for participation in quality assurance activities and standards maintenance 	<ul style="list-style-type: none"> • Evidence and legal accountability requirements • Contractual requirements for participation in quality assurance activities and standards maintenance

	<ul style="list-style-type: none"> Public liability insurance requirements Professional indemnity requirements Office of the Health Services Commissioner OH&S legislative requirements Requirements of the Fair Trading legislation Funding agreements/arrangements with the State to specify adherence to NPAAC standards, participation and enrollment in quality assurance activities Reserve powers of the Chief Health Officer under the Health Act 1958 	<ul style="list-style-type: none"> Public liability insurance requirements Professional indemnity requirements Office of the Health Services Commissioner OH&S legislative requirements Requirements of the Fair Trading legislation Reserve powers of the Chief Health Officer under the Health Act 1958
Other screening services		
	<ul style="list-style-type: none"> Evidence and legal accountability requirements Contractual requirements for participation in quality assurance activities and standards maintenance Public liability insurance requirements Professional indemnity requirements Office of the Health Services Commissioner OH&S legislative requirements Requirements of the Fair Trading legislation Reserve powers of the Chief Health Officer under the Health Act 1958 	<ul style="list-style-type: none"> Evidence and legal accountability requirements Contractual requirements for participation in quality assurance activities and standards maintenance Public liability insurance requirements Professional indemnity requirements Office of the Health Services Commissioner OH&S legislative requirements Requirements of the Fair Trading legislation Reserve powers of the Chief Health Officer under the Health Act 1958
Complaints handling		
	<ul style="list-style-type: none"> Office of the Health Services Commissioner Medical Practitioners' Board of Victoria NATA HIC 	<ul style="list-style-type: none"> Office of the Health Services Commissioner Medical Practitioners' Board of Victoria NATA HIC
Representation on national committees		
Standards setting		
Education assistance/advice		<ul style="list-style-type: none"> Department of Human Services in collaboration with Colleges and Professional Associations Commonwealth/NPAAC Colleges and Professional Associations Commonwealth/NPAAC Department of Human Services (with ability to call upon a of body of experts)

6. Conclusion and Recommendations

The Review Panel has concluded that the Pathology Services Accreditation Act does not conform to the National Competition Policy's Guiding Legislative Principle. That is, it has not been persuaded that the objectives of the Act can only be achieved through the restrictions on competition that the Act imposes. Rather, the Review Panel has formed the view that other, less restrictive alternatives are available that would achieve the Act's underlying objective of ensuring a high level of quality in the delivery of pathology services in Victoria. Moreover, the Review Panel has also formed the view that the Act also fails to meet the principles of good regulation, as outlined earlier in this Final Report.

Consequently, the Review Panel has recommended the repeal of the Act, with its objectives to be achieved through a combination of existing legislative and non-legislative arrangements and the adoption of a limited number of new controls that are less restrictive in nature than the provisions of the existing Act.

The Review Panel has made the following specific recommendations:

It is recommended that the:

1. *Pathology Services Accreditation Act 1984* be repealed. Those pathology services eligible to receive Medicare benefits will continue to be accredited by the Commonwealth Government. Those pathology services ineligible to receive, or do not seek to receive, Medicare benefits will no longer be required to seek accreditation to operate in Victoria.
2. Department of Human Services review all program policy and funding guidelines, health service agreements, service agreements, Memoranda of Understanding, and any other binding agreements under which funding is provided that may directly or indirectly affect the provision of pathology services. Where relevant, these guidelines, Memoranda and agreements should incorporate requirements that the recipients of funding undertake to ensure that:
 - provision of pathology services comply with all relevant NPAAC standards;
 - arrangements for ongoing NATA inspections be organised and maintained; and
 - enrollment and participation in relevant quality assurance programs occur.
3. *Medical Practice Act 1994* be amended so it is a specific ground for misconduct for a medical practitioner to act upon a pathology result when that result has been provided by a pathology service which does not hold NATA or other appropriate accreditation or have an appropriate quality management process in place.



4. Office of the Health Services Commissioner continue to be supported in the work currently undertaken in relation to the conciliation of complaints concerning pathology services. Should the Health Services Commissioner advise the Minister for Health of concerns about the pattern, number or types of complaints received about pathology services, then the Minister for Health should either ask the Health Services Commissioner to investigate these concerns and report findings and recommendations or establish an Advisory Committee to oversee the investigation of these concerns and implement appropriate action.

Any Advisory Committee should be convened on an *ad hoc* basis, in case of need. The Minister for Health would retain discretion to appoint any qualified and suitable individuals to such a committee.

5. Minister for Health seek nominees from the relevant Colleges, professional associations and the industry, generally, from which individuals can be selected to work with the Department of Human Services as expert assistance is required.

6. Minister for Health write to the Commonwealth Minister for Health requesting that all agreements, under which full or partial funding is provided by the Commonwealth to organisations that use these funds to directly or indirectly provide pathology services in Victoria, incorporate requirements that the recipients of funding undertake to ensure that:

- provision of pathology services comply with all relevant NPAAC standards;
- arrangements for ongoing NATA inspections be organized and maintained; and
- enrollment and participation in relevant quality assurance programs occur.

7. Minister for Health nominate representatives to NPAAC and other pathology related committees after requesting a shortlist of nominations from the relevant Colleges, professional associations and the industry, generally.

8. *Health Act 1958* be amended to provide the Chief Health Officer with a series of reserve powers to investigate reports of sub-standard practice by pathology services. Where the Chief Health Officer is of the view that these practices are compromising or posing an immediate danger to public health, then the reserve powers should include the ability for the Chief Health Officer to direct the laboratory to cease operating or conducting specific tests and to notify patients and their medical practitioners and relevant authorities of these concerns.



Appendices

Appendix A:

Terms of Reference – National Competition Policy Review

Review of the Pathology Services Accreditation Act and Pathology Services Accreditation (General) Regulations

The review of the Pathology Services Accreditation Act and Pathology Services Accreditation (General) 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 and Pathology Services Accreditation (General) 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: List of Submissions



Alfred Pathology Service

Australasian Association of Clinical Biochemists Inc.

Australasian Association of Clinical Biochemists Inc. - Victorian Branch

Australian Association of Pathology Practices Inc.

Centre for Advancement of Men's Health and Hepburn Health Service Dalesford

Cohen, Dr Jonathan, Caulfield Family Medical Practice

Commonwealth Department of Health and Ageing, Pathology Section,
Health Access and Financing Division

Confidential submission from an individual

Duckett, Professor Stephen, Dean, Faculty of Health Sciences, La Trobe University

Eastern Health

Faine, Emeritus Professor S., Department of Microbiology, Monash University

Health Services Commissioner

International Diabetes Institute

Masters, Professor Colin, Head, Department of Pathology,
The University of Melbourne

Mayne Health

Medical Scientists' Association of Victoria

Melbourne Pathology

National Association of Testing Authorities, Australia

Network Pathology, Austin & Repatriation Medical Centre

Pathology Services Accreditation Board

Peter MacCallum Cancer Institute

Racing Analytical Services Pty Ltd

The Royal Australian College of General Practitioners Victoria

The Victorian Healthcare Association Limited

The Victorian Infectious Diseases Reference Laboratory

Weedon, Professor David, Chair,
National Pathology Accreditation Advisory Council

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Pathology Services Accreditation Act 1984 (Victoria)

Pathology Services Accreditation (General) Regulations 2001 (Victoria)

Subordinate Legislation (Pathology Services Accreditation (General)

Regulations – Extension of Operation) Regulations 2000 (Victoria)

Subordinate Legislation (Pathology Services (Exempted Tests)

Regulations 1990 – Extension of Operation) Regulations 2000 (Victoria)

Subordinate Legislation Act 1994 (Victoria)



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<<http://www.health.gov.au/npaac/pdf/pathlabs.pdf> >, November 2001.