

Review of the Pathology Services Accreditation Act 1984
Final Report 2003

Victorian Government's response

This document is also available on the Internet at:

<http://www.dhs.vic.gov.au/ahs/legal.htm>

Published by the Victorian Government Department of Human Services, Melbourne Victoria
September 2003

ISBN 07 3116 1858

© Copyright State of Victoria, Department of Human Services, 2003

This publication is copyright, no part may be reproduced by any process
except in accordance with the provisions of the Copyright Act 1968.

(030704/B)

Printed by Big Print, 520 Collins Street, Melbourne

Regulation of Pathology Services in Victoria

Pathology services in Victoria are regulated under both State and Commonwealth legislation. In Victoria it is an offence to undertake pathology testing without accreditation under the Victorian Act. Victoria's Act is therefore a business-licensing scheme. If Medicare reimbursement is sought for a pathology test, then under the Commonwealth's *Health Insurance Act 1973* such a test cannot be paid for by the Commonwealth's Health Insurance Commission (HIC) unless the service is approved (accredited) under that Act.

The overwhelming majority of pathology service providers in Victoria provide services for which a Medicare rebate is sought and, as a result, are regulated under both Commonwealth and Victorian legislation. Victoria is the only State to have its own regulatory framework for pathology services.

Victorian regulation is the responsibility of a statutory authority: the Pathology Services Accreditation Board. Like the HIC, the Board has contracted the National Association of Testing Authorities Australia (NATA) to perform inspections of pathology services on its behalf. NATA reports its findings to both the HIC and the Board, both of which act on NATA's advice.

Review of Victoria's Pathology Services Accreditation Act

A review of the *Pathology Services Accreditation Act 1984* was commissioned in order to meet Victoria's commitments under National Competition Policy to review all legislation that may restrict competition. The review was conducted by a panel of experts, chaired by Mr Don Nardella MP, Member for Melton.

Working within broad terms of reference, the Review Panel considered that it was appropriate and necessary to undertake a wider review of the legislation and its role within the health care system, rather than limiting the review to those provisions that might impede competition. The Review Panel recognized that since the commencement of the Pathology Services Accreditation Act, the environment within which pathology services operate has changed substantially in terms of technology, consumer expectations and awareness, industry structure and the involvement of the Commonwealth Government in the regulation of services for which a Medicare benefit is paid. Further, the Review Panel noted that the Act had not been reviewed since it was assented to in 1984 and acknowledged the need to ensure that existing legislation was assessed against widely held principles of good regulation and the commitment of the Victorian Government to implement regulatory best practices in the public interest.

Review Process

The Review Panel met with the board, a number of pathology service providers and NATA, and produced a discussion paper. The Discussion Paper was widely circulated and 26 submissions were received. Following consideration of the submissions, the Review Panel produced a final report. A copy of the Final Report is attached.

The Final Report of the Review Panel considered the alternatives to the current Victorian pathology services legislation that were presented in its Discussion Paper. Essentially these alternatives can be grouped as follows:

1. Retention of the *status quo*;
2. Establishment of a 'residual' state-based accreditation system for non-Commonwealth accredited pathology services;
3. A negative licensing scheme for all pathology services operating in Victoria; and
4. Repeal of the Victorian legislation.

Findings of the Review Panel

The Review Panel considered that some regulation of pathology providers is needed as there is substantial risk of harm to patients if pathology services are of poor quality. It found that there has been deliberate alignment of the State and Commonwealth accreditation systems in order to minimise effective duplication. For the vast majority of Victorian pathology services that are subject to dual accreditation requirements, the Review Panel considered that, in practice, the additional layer of State regulation provided no additional protection for public health. It also considered that it was neither justifiable in terms of risks to public health, nor practicable in terms of cost, to maintain a business-licensing régime for the small number of Victorian pathology services that are not subject to Commonwealth regulation.

The Review Panel also concluded that:

- (a) the current legislation is likely to have had substantial negative impacts on the supply of screening services with probable negative impacts on public health. It considered that the risk to the public posed by such services is unlikely to be sufficient to justify the need for accreditation, and the cost of accreditation deters small organisations such as community health centres from offering screening services; and
- (b) the legislation does not appear to have been effective in substantially improving the quality of pathology services supplied in Victoria.

The Review Panel has therefore recommended that the Victorian Act be repealed. Its other key recommendations are that:

- (a) NATA accreditation and compliance with the National Pathology Accreditation Advisory Council (NPAAC) standards should be made a condition of funding for any State or Commonwealth funded pathology services operating in Victoria;
- (b) the *Medical Practice Act 1994* should be amended to require medical practitioners to ensure that they only use accredited pathology services; and
- (c) the *Health Act 1958* be amended to provide the Chief Health Officer with "reserve powers" to investigate reports of sub-standard practices by pathology services. Where the Chief Health Officer forms the view that these practices are posing an immediate risk to public health, he or she should have the ability to direct the laboratory to cease operating or conducting specific tests and to notify patients and medical practitioners of this action.

The Review Panel's report was provided to the Minister for Health in February 2002. However, consideration of the recommendations was deferred temporarily because a review of the Commonwealth's accreditation processes was underway.

Review of the Commonwealth's accreditation arrangements

During the course of the Victorian review, the Commonwealth commenced a review and evaluation of its pathology laboratory accreditation arrangements.

The review report entitled, *Evaluation of the Australian Pathology Laboratory Accreditation Arrangements* (Commonwealth Department of Health and Ageing) was released in July 2002. It found that the Commonwealth's arrangements are fundamentally compatible with modern approaches to health care safety and quality and are underpinned by strong and constructive medical and scientific cultures. The review also found qualitative evidence that the quality of pathology services has significantly improved since national accreditation arrangements were introduced in 1986.

However, the review report pointed to the need to enhance the accreditation process and identified some room for improvement in the Commonwealth's regulatory and administrative framework. In particular, it stressed the need to address delays in the management of non-compliance with relevant standards by a small number of laboratories.

The Commonwealth's review also noted that, because the Commonwealth can only regulate pathology services through its administration of the Medicare Benefits Scheme, a small number of pathology services that do not attract Medicare benefits remain unregulated. The review recommended that the Department of Health & Ageing work with the States and Territories to evaluate the need for, and potential costs and benefits of, any additional legislation in all jurisdictions to complement national accreditation arrangements.

The Commonwealth has accepted the review report's recommendations and has moved quickly to implement them. For instance, there is a strengthened Deed of Agreement between NATA and the HIC. Additionally, on 1 January 2003, a new determination under the *Health Insurance Act 1973* took effect setting out new statutory principles to guide the exercise of the Commonwealth's power to grant, vary or revoke an application for approval of premises as an accredited pathology laboratory. The new principles considerably strengthen the HIC's ability to rely on NATA's advice in determining whether to grant, vary or revoke approval of premises as an accredited pathology service for Medicare rebate purposes.

The Commonwealth is seeking the support of States and Territories to explore through the Australian Health Ministers' Advisory Council the need for, and costs and benefits of, any additional State legislation to complement the Commonwealth's régime.

The Commonwealth's report, new principles and information about Commonwealth accreditation arrangements in relation to pathology services are available on the Internet at the following address: <http://www.health.gov.au/haf/branch/dtb/pres.htm>

Government Response to Victorian Review

In light of the findings of the Review Panel and subsequent actions taken by the Commonwealth to enhance its regulation of the pathology services industry, the Victorian Government agrees to repeal the Pathology Services Accreditation Act.

Victoria will support the Commonwealth's proposal for all jurisdictions to examine the need for, and costs and benefits of, any regulation to complement the Commonwealth's arrangements. This provides an opportunity to achieve a nationally consistent approach to the regulation of those pathology services which are not captured by the Commonwealth's regulatory régime.

The Government will act to strengthen the Department of Human Services' (DHS) policy capacity in relation to pathology issues, and will put in place arrangements to seek expert external advice when required. DHS will ensure that publicly funded pathology services are subject to appropriate accreditation and quality standards. DHS will work with the Office of the Health Services Commissioner and the Medical Practitioners' Board of Victoria to examine any trends in relation to complaints about pathology services and determine what action should be taken to address public health concerns.

The Government agrees with the thrust of the Review Panel's recommendation regarding amendments to the *Medical Practice Act 1994*. However, the Government recognises further consideration will need to be given to this recommendation, including consultation with the Medical Practitioners' Board of Victoria. This recommendation could also be further considered in the context of any national work on complementary State/Territory legislation.

The Review Panel has also recommended strengthening the reserve powers of the Chief Health Officer. This recommendation was made before the outcomes of the Commonwealth review process. Further, the Victorian Review Panel did not find evidence of any significant public health problems in relation to Victorian pathology services that are not Commonwealth accredited. Accordingly, at this point in time, there is currently insufficient evidence to suggest that conferring such broad powers on the Chief Health Officer would be warranted. The Victorian Government would prefer to first explore on a national basis what cost effective mechanisms could be implemented to complement the Commonwealth's accreditation régime. It supports the proposal to undertake the necessary work through the Australian Health Ministers' Advisory Council.

A summary response to each of the Review Panel's recommendations is outlined in the attached table.

Summary of the Review Panel's Recommendations and Government's Response

Recommendation	Government's Response
<p>1. The <i>Pathology Services Accreditation Act 1984</i> 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.</p>	Agree
<p>2. The 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:</p> <ul style="list-style-type: none"> • 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. 	Agree
<p>3. The <i>Medical Practice Act 1994</i> 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.</p>	Agree in principle subject to further consideration on the form that any changes to the Act would take and subject to consultation with the Medical Practitioners' Board of Victoria.
<p>4. The 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 those concerns and report findings and recommendations or establish an Advisory Committee to oversee the investigation of those concerns and implement appropriate action.</p>	Agree to continue to support the work of the Office of the Health Services Commissioner and to utilize existing arrangements available under the <i>Health Services (Conciliation and Review) Act 1987</i> to investigate concerns in relation to complaints received about pathology services.
<p>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.</p>	

Recommendation

Government's Response

5. The 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.	Agree
6. The 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: <ul data-bbox="181 779 710 1014" style="list-style-type: none">• 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.	Agree
7. The 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.	Agree that nominations will be sought when required
8. The <i>Health Act 1958</i> 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 those concerns.	This recommendation was made before the Commonwealth implemented a series of changes to its national accreditation arrangements for pathology services. Accordingly, the Government would prefer to first explore what mechanisms could be used to complement the Commonwealth's accreditation régime and support any work that may be undertaken by jurisdictions through the Australian Health Ministers' Advisory Council.
