Patient Safety Law:
From Silos to Systems

Appendix 2: Country Reports
AUSTRALIA

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Financial contribution from the Health Policy Research Program, Health Canada HPRP 6795-15-5760009. The views expressed herein do not necessarily represent the official policy of Health Canada. March 31, 2006

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Australia

Australia is a constitutional monarchy with a three-tiered political system. The first level is the federal Australian or Commonwealth government, the next level consists of the six state and two territorial governments and the third is local government.[1] Australia has a population of 20.1 million.

Health Care System Context

Law

Australia has a common law system of law.

Health

The foundations of the Australian health care system are: universal tax-financed health care; a strong 'stewardship' role for government; commitment to social solidarity and equity; and concerns about efficiency and quality.[2]

Health Services Delivery

Australia has a complex health system with many providers and a range of financial and regulatory mechanisms. The Commonwealth funds rather than provides health services. The states and territories, with Commonwealth financial assistance, fund and administer public hospitals, mental health services and community health services and regulate health workers. The Australian Health Care Agreements (AHCA) between the Commonwealth and the states/territories for the funding of public hospitals are negotiated every five years.[3] There is a substantial private sector and private sector funding accounted for 1/3 of all health expenditure in

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[1] Austl., Commonwealth, "Government in Australia", online: <http://www.australia.gov.au /govt-in-aust>.

[2] Melissa Hilless & Judith Healy, "Health Care Systems in Transition Australia" (Copenhagen, European Observatory of Health Care Systems, 2001) at 90.

[3] The agreements operate under the Commonwealth *Health Care (Appropriation) Act 1998* (Cth.). The Act specifies the maximum level of Commonwealth funding, and makes grants subject to conditions specified in the ACHAs. Under section 6 of the Act, grants to States/Territories are not payable unless certain health care principles are adhered to, such as eligible individuals can choose to receive hospital services free of charge as public patients, access to these services is to be based on clinical need and provided within a clinically appropriate timeframe and equitable access is to be provided to these services regardless of geographical location. *Health Care (Appropriation) Act 1998,* online: ComLaw <http://www.comlaw.gov.au>. See also 2002-03 *Health Care (Appropriation) Amendment Bill 2003*, Bills Digest No. 162 , online: Parliament of Australia's Parliamentary Library: <http://www.aph.gov.au/library/pubs/bd/2002-03/03bd162.htm>

the late 1990s.[4] Private hospitals account for 30 percent of the beds in the Australian hospital system and most physicians are engaged in private practice to a greater or lesser extent. Governments exert leverage in that they fund 70 percent of the total health care expenditure. The Commonwealth funds 48 percent of that amount.[5]

The 1901 Constitution regarded health care as the responsibility of the states and granted powers to the Commonwealth only in respect of quarantine to prevent those with diseases entering Australia. The influenza epidemic in 1918 pointed to a coordination role for the Commonwealth in public health and so the Commonwealth Department of Health was established with the agreement of the states in 1921. The Australian Constitution was amended in 1946 to enable the Commonwealth to make laws in respect of "the provision of maternity allowances, widows pensions, child endowment, unemployment, pharmaceutical, sickness and hospital benefits, medical and dental services (but not so as to authorize any form of civil conscription [i.e. medical and dental practitioners cannot be compelled to work for the government or to provide services for a proscribed fee]), benefits to students and family allowances."[6] The *National Health Act 1953*[7] consolidates the four main post-war pillars of the Australian health care system: the pharmaceutical benefits scheme; the hospital benefits scheme; pensioner medical services; and the medical benefits scheme (subsidized medical costs of those in non-profit health insurance schemes).

A Medibank scheme was introduced in 1975 and the much amended program was replaced with the current Medicare scheme in 1983. Medicare is a universal, tax-funded health insurance system funded by a mandatory levy of 1.5% on income. It provides subsidized or in most cases free access to a doctor of choice, free public hospital care, and subsidized pharmaceuticals. Private insurance is encouraged through the use of financial incentives.

The Commonwealth government is a major funder, policy-maker, planner and regulator. It is specifically responsible for the safety and quality of drugs and therapeutic goods, for public and private health insurance and national health strategies. The Department of Health and Ageing is the principal national agency in the health sector. It is concerned with national policy and funding, public health, research and information management. In 2004 it had the following divisions: population health, primary care, acute care, aging and aged care, medical and pharmaceutical services, portfolio strategies, Office for Aboriginal and Torres Strait Islander health, health services improvement, Information and Communications and Business. It also houses the National Health and Medical Research Council (research funding body), Commonwealth Rehabilitation Services and the Therapeutic Goods Agency. There are a number of other health related regulatory actors:

- The Health Insurance Commission (administers Medicare)
- Australian and New Zealand Food Authority (food quality and labeling standards)

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[4] Hilless & Healy, *supra* note 2 at 24.
[5] Hilless & Healy, *supra* note 2 at 27.
[6] *Commonwealth of Australia Constitution Act* , s 51(xxiiiA).
[7] A much amended version is still in force. *National Health Act 1953,* (Cth.) online: ComLaw <http://www.comlaw.gov.au>

- The Australian Radiation Protection and Nuclear Safety Agency (protecting health and safety of people and the environment from the harmful effects of radiation)
- The Department of Veterans' Affairs (funds compensation, income support, health services, allied health and counseling and community support)
- Australian Institute of Health and Welfare (independent statistics and research agency)
- Australian Health Ministers' Conference (annual) and the Australian Health Ministers' Advisory Council (officials)
- Council of Australian Governments (coordinates the activities of Commonwealth, state and territorial governments at the highest level).

At the state/territory level, health departments undertake policy-making and budgeting, performance standard setting, the administration of public hospitals, mental health services, dental health services, child, adolescent and family health services, women's health programmes, health promotion; rehabilitation services; home and community care; and the regulation, inspection, licensing and monitoring of services and personnel. There is some variance in regulatory approaches and program delivery across states. For example, the extent of the regulation around the licensing of private hospitals differs from state to state with market-oriented governments preferring lighter regulation.[8] Due to the plethora of states and territories in Australia, we are examining the regulatory framework in only one state throughout the report – Victoria.[9]

Given the division of powers, the ability of any one sector to plan and regulate is limited. Increasing use is made of intergovernmental programs to achieve collaborative action. The Australian Health Ministers Conference[10] in 2004 agreed to the following:

- all public hospitals will use the "5 step patient, right side, right procedure protocol"
- by mid-2005, all public hospitals will introduce new incident management systems to monitor, analyze and guide their actions in dealing with safety and quality incidents
- by the end of 2005, all public hospitals will be required to report all sentinel events and contribute to a national report on sentinel events, as well as have a patient safety risk management plan in place
- all public hospitals will use a common medication chart by June 2006
- by the end of 2006, all public hospitals will have a pharmaceutical review process for medication prescribing, dispensing, administration and documentation processes
- all patients will receive an information booklet on safety when admitted to a public hospital.[11]

However, it is not clear what policy tools will be used to implement these steps.

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[8] Hilless & Healy, *supra* note 2 at 27.

[9] Victoria was chosen because of the substantial history, scope and nature of its governance mechanisms used to address patient safety.

[10] Comprised of all Australian federal, state and territory and New Zealand health ministers, the conference provides a forum for the discussion of health policy and the promotion of a nationally consistent approach to health policy implementation. Conference decisions are reached by consensus and the Conference does not have statutory powers. Australian Health Ministers' Advisory Council, online: <www.ahmac.gov.au/site/home.asp>.

[11] Austl., Commonwealth, Department of Health and Aging, Australian Health Ministers' Conference, "Health Ministers Agree to Reform Agenda" (23 April 2004), online:< http://www.health.gov.au>.

The Australian Council on Safety and Quality in Health Care was established in 2000 by Commonwealth (funds 50 percent) and state/territory (funds 50 percent on a per capita basis) health ministers to provide national leadership and system wide approaches to safety and quality improvement in health care.[12] It was established for five years and its life was extended a further year by an agreement between the states/territories and the federal government. It is a policy advisory body that influences change through a collaborative "third-party broker" approach and identifies, coordinates and funds action at all levels of the health care system. It can only make recommendations, not mandate action or change, as it has no devolved regulatory powers. The Council has developed national standards on the definition of sentinel events, credentials and clinical privileges, and open disclosure through collaborative engagements with stakeholders. One of the issues for the Council as it progresses is "it has limited operational capacity and lacks statutory authority to embed a culture of safety at all levels".[13]

In 2004 the Health Ministers Conference commissioned a Review of Future Governance Arrangements for Safety and Quality in Health Care. The review team reported back in 2005.[14] The report recognized that the Council has been very successful in increasing providers' and administrators' awareness of safety and quality issues and how to address them and therefore contributing to a process of cultural change. It also recognizes that the Council through its work has elevated the importance of the systems approach to safety and quality. It has also produced an extensive body of policy work. However, it notes that due in part to the way it was set up, it was not always able to communicate this information effectively, did not have the authority to implement it, and had a somewhat narrow focus on the acute centre.[15]

The review recommended the development of another national body, with clearly defined purpose and functions, effective links with jurisdictions and key-stakeholders and the capacity to provide advice that is implementable. The new body should:

- lead and coordinate improvements in safety and quality in health care by identifying issues and policy directions, recommending priorities for action, disseminating knowledge and advocating for safety and quality.
- report publicly on the state of safety and quality, including performance against standards.
- recommend national data sets for safety and quality.
- provide strategic advice to health ministers on best practice.
- recommend nationally agreed standards for safety and quality improvement.

It did not recommend that this be a regulatory body, noting that reviewers believed that Australia's federal system would make such a regulatory body unworkable. The reviewers also

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[12] Bruce B. Barraclough, "Advancing the Patient Safety Agenda: An Australian Perspective" (New York: The Commonwealth Fund, 2004) at 5.
[13] *Ibid.*at 9.
[14] Ron Patterson et al, "National Arrangements for Safety and Quality of Healthcare in Australia: The Report of the Review of Future Governance Arrangements for Safety and Quality in Health Care" (Canberra: Commonwealth Department of Health and Aging, 2005), online:
<http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-sqreview.htm>.
[15] *Ibid* at 9.

believe that public reporting is an under-utilized driver of change and should be given an opportunity to transform the safety and quality before moving to more regulation.[16]

Health Ministers specifically asked the review team to examine accreditation as a safety and quality driver. The review panel agreed that there were problems with accreditation as currently constituted in Australia and that it needed to be reformed to enhance quality improvement and to assist with the implementation of national standards.[17]

The Australian Council on Safety and Quality in Healthcare ceased operations on 31 December 2005 and from 1 January 2006, the Australian Commission on Safety and Quality in Health Care succeeds it. The Commission is to report to Health Ministers. The web-site of this new Agency states:

Ministers agreed that the new Commission will build on the achievements of Council and the transition to new arrangements will ensure this valuable work is not lost. While attention on improving the safety of hospitals will be maintained, quality improvement in primary health care and the private sector will also become priority areas. Achieving safe, effective and responsive care for consumers will be a key objective of the Commission.**[18]**

Ministers have also approved an Inter-Jurisdictional Committee to provide advice to the Commission on the feasibility of implementation of safety and quality reforms. The group will be comprised of representatives of current senior executives from each state and territory who are connected to decision-making processes within their respective jurisdictions.[19]

The Commission's functions are to:

- lead and coordinate improvements in safety and quality in health care in Australia by identifying issues and policy directions, recommending priorities for action, disseminating knowledge, and advocating for safety and quality;
- report publicly on the state of safety and quality including performance against national standards;
- recommend national data sets for safety and quality, working within current multilateral governmental arrangements for data development, standards, collection and reporting;
- provide strategic advice to Health Ministers on 'best practice' thinking to drive quality improvement, including implementation strategies; and
- recommend nationally agreed standards for safety and quality improvement.[20]

However, this new agency is still in its formative stages and little other information about its functions is available at present.

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[16] *Ibid.* at v.
[17] *Ibid.* at viii.
[18] Australian Commission on Safety & Quality in Health Care, "Home", online: <http://www.safetyandquality.org/>.
[19] Australian Health Ministers Advisory Council, "Public Communique: Australian Commission on Safety and Quality in Health Care Set to Commence" (2005), online: Australian Commission on Safety and Quality in Health Care <www.safetyandquality.org/page0001.htm>.
[20] Australian Commission on Safety & Quality in Health Care "Consumer Advisory Committee", Powerpoint Presentation (November 2005), online: <http://www.safetyandquality.org/page0001.htm>.

Performance

The Commonwealth Fund's International Working Group of Quality Indicators compares forty quality indicators from five countries: Australia, Canada, New Zealand, the United Kingdom and the United States.[21] Each country studied had different areas of good performance and weakness. Australia had high cancer survival rates, except childhood leukemia, especially for cervical cancer and non-Hodgkin's lymphoma. Breast and cervical screening rates were high. Asthma mortality was relatively low. Influenza and polio vaccination rates were high. Rates of access to physicians and physician responsiveness were high. Whooping cough rates were much higher than other countries.

The World Health Organization examined the relative performance of health systems of member countries.[22] Overall health system attainment (this measures the level of health, the distribution of health, the level of responsiveness, the distribution of responsiveness and the fairness of financial contribution) was one of the indicators measured. The report estimated that Australia ranked twelve on the list (Canada 7, U.S. 15, Denmark 20, the United Kingdom 9 and N.Z. 26).[23] The study also examined how efficiently health systems translate expenditure into health in regard to the overall achievement to expenditure. Australia ranked number 32 in the world (Canada 30, the United Kingdom 18, Denmark 34, the U.S. 37 and New Zealand 41).[24] The responsiveness of health systems was also examined in regard to the level of responsiveness (defined as dignity, autonomy, and confidentiality, and prompt attention, quality of basic amenities, access to social support networks during care and the choice of care provider). Australia ranked 12-13 (the U.S. 1, the U.K. 26-27 (with Qatar), Denmark 4, Canada 7-8, and New Zealand 22-23). In terms of distribution of responsiveness (disadvantaged groups), Australia ranked 3rd equal with 37 other countries, including the U.K. U.S., N.Z., Canada, and Denmark.

Patient Safety

Key Statistics

The Quality in Australian Health Care Study (1995) examined the incidence of adverse events in Australian hospitals. It concluded that 16.6 percent of patients experienced adverse events in Australian hospitals and 50 percent of these events were preventable. Three percent of the adverse events resulted in death or permanent disability. The study was later reanalyzed using

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[21] Commonwealth Fund International Working Group on Quality Indicators, *First Report and Recommendations of the Commonwealth Fund's International Working Group on Quality Indicators* (New York: The Commonwealth Fund, 2004) online: Commonwealth Fund <http://www.cmwf.org>.

[22] The World Health Organization, *The World Health Report 2000,* (Geneva: The World Health Organization, 2004).

[23] *Ibid.* at 152-155. Because of statistical uncertainty, Canada, the U.K. and Australia are in the same range with less than 0.5 percent difference between them.

[24] *Ibid.* at 152-155. Canada, Australia and Denmark are in the same range.

the methodology used in the U.S. and using this methodology the adverse event rate was 10.6 percent. The study resulted in action by federal and state governments to address issues related to patient safety and healthcare quality.

Institutional Regulation

Institutional regulation is generally a function of the states and territories. However, residential care for the aged is primarily financed and regulated by the federal government.[25] Section 51 (xxiiia or 23A) of the Constitution gives the Commonwealth power to make laws relating to aged care.[26] By empowering the Commonwealth to 'provide' a range of health-related personal allowances and benefits, this section permits the Commonwealth to fund individuals to stay in nursing homes and thus to exercise significant control over payment terms and impose regulatory standards.[27]

Nursing homes that receive federal funding are governed by the requirements of the Commonwealth *Aged Care Act 1997*[28] and its subordinate legislation, the various Aged Care Principles.[29] The Act puts in place a quality assurance framework in which homes seeking funding must first be accredited against a set of legislative standards by an independent agency established by the Commonwealth government.

In Victoria, the *Health Services Act 1988*[30] and regulations pursuant to this Act contain the regulatory framework for public and private hospitals, community health centres, day procedure centres and supported residential services (accommodation, personal or nursing care). Its objectives are to ensure that:

- health services provided by health care agencies are of high quality
- an adequate range of essential services is available to all persons resident in Victoria
- public hospitals are governed and managed effectively, efficiently and economically
- public funds are used effectively by health care agencies and are allocated according to need
- purchasing arrangements for public hospitals provide value for money
- health care agencies are accountable to the public

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[25] Austl., Commonwealth, Department of Health and Ageing, "Aged Care in Australia - August 2003: Introduction", online: <http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/ageing-about-agedaust-agedaus1.htm>.

[26] Bernard Pulle, Economics, Commerce and Industrial Relations Group, Commonwealth (Austl.), *Proposed Changes to Financing Aged Care - Some Tax and Constitutional Issues,* Current Issues Brief 28 1996-97, online: <http://www.aph.gov.au/library/pubs/CIB/1996-97/97cib28.htm>.

[27] University of Melbourne Law School, Centre for Comparative Constitutional Studies, *Implementation options for National Legislative Schemes in Public Health: Revised Final Paper* (7 September 1999), online: <http://www.dhs.vic.gov.au/nphp/workprog/lrn/legtools/options.pdf> at 7-8.

[28] *Aged Care Act 1997,* (Cth.), online: ComLaw <www.comlaw.gov.au> [*ACA*].

[29] *Ibid.,* s. 96-1.

[30] *Health Services Act 1988,* (Vic.), online: Victorian Legislation and Parliamentary Documents <http://www.dms.dpc.vic.gov.au> [*HSA 1988*].

- users of health services are provided with sufficient information in appropriate forms and languages to make informed decisions about health care
- health care workers are able to participate in decisions affecting their work environment
- users of health services are able to choose the type of health care most appropriate to their needs.[31]

The legislation also sets out a set of principles applying to hostels, nursing homes and supported residential services:[32]

- residents are entitled to high quality health care and personal care, to their choice of medical practitioner or other provider of health care services and to an informed choice of appropriate treatment
- residents should be provided with a sufficient level of nutrition, warmth, clothing and shelter in a home like environment
- services should be provided in a safe physical environment and the resident's right to participate in activities involving a degree of risk should be recognized
- residents should be treated with dignity and respect and are entitled to privacy
- residents should be provided with and be encouraged to participate in activities appropriate to their interests and needs and to physical and social rehabilitation
- residents are entitled to social independence including the right to choose and pursue friendships with members of either sex, to practice religion and cultural customs and to exercise rights as citizens
- residents are entitled to the right to manage their own finances wherever possible
- residents are entitled to freedom of choice to the extent that it does not unreasonably infringe the rights of others and the freedom to comment about the provision of health services.

Principles for public hospital services (or for services provided to publicly funded patients by private operated hospitals) are contained in the health care agreements between the Commonwealth and Victoria and are established as guidelines.[33] The *Health Services Act 1988* permits the Minister to create guidelines in respect of a number of issues, including the improvement of the quality of health care and health facilities.[34] The guidelines are approved by the Governor in Council and published in the Gazette. The guidelines have a three year life before they expire. It is unclear whether these have the status of regulations or are quasi-regulatory in nature. It is also unclear how they are enforced.

Private hospitals, day procedure centres and supported residential services must be registered under the *Health Services Act 1988*.[35] Before granting registration, the Department of Human Services (DHS) must consider whether appropriate arrangements will be in place to maintain,

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[31] *Ibid.,* s. 9.
[32] *Ibid.,* s. 10.
[33] *Ibid.,* s. 17AA.
[34] *Ibid.,* s. 12(b).
[35] *Ibid.,* s. 111.

monitor, evaluate and improve the quality of services offered by the establishment.[36] Whether the quality of care has been satisfactorily maintained is a consideration for registration renewal.

Standards

If a nursing home wishes to receive Commonwealth funding, it is required to be accredited against standards set out in the Commonwealth *Quality of Care Principles 1997*.[37] They concern the following matters: management systems, staffing and organizational development; health and personal care; resident lifestyle; physical environment and safe systems. These four accreditation standards are further subdivided into 44 expected outcomes. The standards do not prescribe how a facility is to achieve an outcome and are intended to give providers flexibility in determining how to best meet residents' needs.[38] In addition to requiring compliance with the standards, the legislative framework also obliges accredited providers to undertake a process of continuous improvement to be measured against the standards.[39]

The Aged Care Standards and Accreditation Agency (ACSAA) is an independent company established by the Commonwealth government and designated as the accreditation body under the *Aged Care Act 1997*.[40] Its role is to accredit and supervise all Commonwealth funded nursing homes. In particular, it manages and undertakes the accreditation process, promotes quality care, manages services trying for accreditation, and liaises with the Department of Health and Ageing. The accreditation period is a maximum of four years but may be less if there are good reasons for more frequent checks.[41] The Agency reports non-compliance or failures to achieve the required standard to the Department of Health and Ageing. The Act sets out sanctions the Department can impose.[42] Sanctions can range from the withholding of Commonwealth funding for new residents to the revoking of a facility's approval to be a provider of aged care services.

A Senate Inquiry into aged care that reviewed the performance and effectiveness of the ACSAA noted that there is anecdotal evidence to suggest the quality of care provided in aged care facilities has improved since accreditation was introduced, although there is little systematic data to show how accreditation has influenced quality of care and a number of concerns about the

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[36] *Ibid.,* s. 83 (1).
[37] *ACA, supra* note 28, ss. 42-1(1)(c), 54-2; *Quality of Care Principles 1997,* (Cth.), Schedule 2, "Accreditation Standards" [*Quality of Care*].
[38] Austl., Commonwealth, The Senate Community Affairs Committee, *Quality and equity in Aged Care*, (June 2005), s. 3.7, online: <http://www.aph.gov.au/Senate/committee/clac_ctte/aged_care04/report> [Senate Report].
[39] *Accreditation Grant Principles 1999*, (Cth.), s. 3.19 [*AGP*]. Under s. 3.19, accredited providers must submit a written continuous improvement plan to the agency. The active pursuit of continuous improvement is an expected outcome for each of the four Accreditation Standards.
[40] The Aged Care Standards and Accreditation Agency Ltd., "About the Agency", online: <http://www.accreditation.org.au/AboutTheAgency> [ACSAA].
[41] Most homes are accredited for three years. Of the 2949 accredited homes as of 30 June 2004, 90% were accredited for three years while only 6 homes received four year accreditation, Senate Report, *supra* note 38, s. 3.10. The *AGP*, *supra* note 39, s. 2.11 (3) stipulates that commencing residential care services must be accredited for 12 months.
[42] *ACA, supra* note 28, s. 66-1. The Department places information about sanctions imposed on facilities on their website: <http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/ageing-rescare-sanction-sanccur.htm>.

system were raised during the inquiry.[43] The inquiry held that the accreditation standards are unable to effectively measure care outcomes because they are too general and recommended that the standards be reviewed so that expected outcomes are defined in more precise terms.[44]

In the state of Victoria, all public hospitals must undergo accreditation as of 1 July 2000.[45] They can seek accreditation through:

- The Australian Council on Healthcare Standards' Evaluation and Quality Improvement Program (ACHS EQuIP)
- The International Organization for Standardisation's Quality Management System 9000 (ISO 9002)
- Quality Improvement Council's Health and Community Service Standards (QIC)[46]

The policy objective behind mandatory accreditation is "continuous maintenance of appropriate standards of care and quality improvement."[47] Accreditation surveys are to be forwarded by the hospital to the DHS within two weeks.[48] Only high priority recommendations from accreditation reviews need to be sent to the Department. A report by the Victorian Auditor General on managing patient safety in public hospitals noted that under the ACHS system, a number of hospitals were accredited despite having weak clinical risk management systems, as clinical risk management requirements were not mandatory until the beginning of 2005.[49]

Minimum standards for private hospitals and day procedure centers are contained in the *Health Services (Private Hospitals and Day Procedure Centres) Regulations 2002*.[50] They include provisions outlining adequate staffing levels, complaints system and infection control plan requirements, and hygiene/suitability requirements for facilities and equipment. The DHS conducts site visits of registered facilities.[51]

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[43] Senate Report, *supra* note 38, ss. 3.16-3.22. Supported by the Agency and the Department, a project evaluating the impact of accreditation on quality of care is expected to be completed in 2006.
[44] Senate Report, *supra* note 38, ss. 3.124-3.125.
[45] Austl., Victoria, Department of Human Services, "Public Hospital Accreditation in Victoria", online: <http://www.health.vic.gov.au/accreditation/index.htm>. Accreditation was a contractual requirement in the Health Services Agreement between DHS and Public Hospitals in 2003-04. In 2004, new relational agreements called Statement of Priorities were introduced for certain hospitals and in at least one of these agreements, maintaining accreditation is a quality performance priority. Accreditation is also a requirement in the current Victorian Policy and Funding Guidelines: Austl., Victoria, DHS Public Hospital Governance, "Health Service Agreement – Hospitals 2003-2004", s. 10, online: < http://www.health.vic.gov.au/governance/s1-4hospital.pdf> [Victoria Guidelines]. Austl., Victoria, DHS Public Hospital Governance, "Statement of priorities 2004-05 Agreement between the Minister for Health and Austin Health" at 7, online: < http://www.health.vic.gov.au/governance/sop.htm>. Austl, (Vic.), Victorian Government Department of Human Services, "Victoria – Public hospitals and mental health services and funding guidelines 2005-2006" (June 2005) at 39.
[46] For more information on these individual systems, see their websites: ACHS <www.achs.org.au>; QIC <www.qic.org.au>; ISO 9002 <http://www.iso.org>.
[47] Public Hospital Accreditation in Victoria, *supra* note 45.
[48] Victoria Guidelines, *supra* note 45 at 39.
[49] Austl., Victoria,. Auditor General, *Managing patient safety in public hospitals* (March 2005) at 82 [AG Report].
[50] (Vic.).
[51] Austl., Commonwealth, Victorian Government Health Information, "Private Hospitals in Victoria", online: <www.health.vic.gov.au/privatehospitals/general.htm >.

Funding and Accountability Mechanisms

A mechanism for arranging Commonwealth funding for public hospitals, the Australian Health Care Agreements also act as a means of promoting a national approach to public health care delivery and reforms in the system.[52] One objective of the current agreements is to "improve the focus of public hospital services and mental health services on safety, quality and improved patient outcomes."[53] Under the agreements, jurisdictions must have in place independent complaints bodies and Public Hospital Patient Charters.[54] Jurisdictions also agree to implement service delivery changes demonstrated to improve patient care, patient safety and patient outcomes in an open and consultative manner.[55] Transparency and accountability are sought through performance reporting requirements that jurisdictions must satisfy in order to qualify for full funding.[56] The Commonwealth government publishes performance data against agreed indicators in an annual report to the public.[57] The current agreement also sees the states and the Commonwealth agreeing to work together to develop and refine performance indicators, including measures of health care quality and safety, such as adverse events.[58]

Funding agreements between the state or territorial government and hospitals may also include requirements in respect of safety or quality. In Victoria, the boards of public health services[59] and the Minister of Health are required by the *Health Services Act 1988* to agree on a Statement of Priorities for each financial year.[60] These Statements must contain the objectives, key performance outcomes and indicators/targets the service will be assessed and monitored against, as well as reporting requirements.[61] A public health service's ability to meet the criteria in its Statement of Priorities is a factor in determining whether it will receive public funds or conditional public funding.[62] All other hospitals will be governed by the DHS Health Service

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[52] Austl., Commonwealth, Department of Health and Ageing, *Australian Health Care Agreements: Performance Report 1998-99 to 2002-2003* (Caberra: Department of Communications, Information Technology and the Arts, 2004) at 134.

[53] Austl,, Commonwealth & Victoria, *Australian Health Care Agreement between Commonwealth of Australia and the State of Victoria (2003-2008)*, online: Victorian Government Health Information <http://www.health.vic.gov.au/agreement/index.htm>, s. 8 [*Agreement*]. A part of the 1998-2003 agreements was the Quality Improvement and Enhancement Plan, which targeted funding to support improvements in safety and quality.

[54] *Ibid.,* Schedule D,

[55] *Ibid.,* s. 17.

[56] *Ibid.,* s. 25.

[57] *Ibid.,* Schedule C, s. 4 , Attachment A lists minimum performance indicators to be published. Indicators of quality on this list are public hospital accreditation status and the number of accreditated medical specialist training positions.

[58] *Ibid.,* Schedule C, ss. 12, 13 (c).

[59] Victoria's large regional and metropolitan hospitals are grouped into bodies called public health services and are listed under Schedule 5 of *the HSA 1988.* AG Report, *supra* note 49 at 19.

[60] *HSA 1988*, *supra* note 30, s. 65ZFA. The Statement of Priorities were introduced in 2004, based on recommendations made by the Victorian Public Hospital Governance Reform Panel. They are relational documents that replace the previous contractual Health Service Agreements. They also apply to 3 denomination hospitals. Austl., Victoria, "Statement of Priorities: 2004-05" at 13, online: <www.health.vic.gov.au/governance/sop.htm>; Austl., Victoria, Victorian Department of Human Services, *Victoria –Public Hospitals and mental health services: Policy and funding guidelines 2005-2006* (Melbourne: Big Print, 2005), online: Metropolitan Health and Aged Care Services Division <http://www.health.vic.gov.au/pfg> [Guidelines 05-06].

[61] *HSA 1988,supra* note 30*,* s. 65ZFA.

[62] *HSA 1988, supra* note 30*.,* s. 18(ec).

Agreement, a contractual agreement that in the past has required compliance with safety and quality requirements in the Victorian public hospital policy and funding guidelines.[63] Before granting public funds to any agency, the government must consider the arrangements in place for monitoring and improving the quality of the provider's health services.[64]

The Victorian DHS public hospital policy and funding guidelines require public hospitals to have a quality framework, which should include quality and safety programs such as accreditation, clinical risk management and infection control.[65] Hospitals are required to submit a Patient Safety Risk Management Plan and make available publicly an annual Quality of Care Report.[66]

The *Health Services (Governance and Accountability) Act 2004* amended the *Health Services Act 1988* to implement some of the recommendations of the Victoria Public Hospital Governance Reform Panel of 2003. It aims to clarify the respective roles and responsibilities of boards, CEOs, the Minister and Secretary of the Department of Human Services. It also reorganizes hospitals to ensure that service is provided efficiently. The amendments give the Secretary the power to audit public hospitals to determine whether they are providing high quality health services.[67] The Minister can also issue binding directives to boards if it will give effect to the objectives of the *Health Services Act 1988* or appoint a delegate to public hospital boards if it will assist in improving their performance.[68]

Monitoring Mechanisms

Monitoring is conducted at the federal and state/territory level.

The Aged Care Standards and Accreditation Agency monitors the performance of aged care facilities against the Commonwealth accreditation standards. Monitoring processes, responsibilities and timelines are outlined in the *Accreditation Grant Principles 1999* and *Accountability Principles 1998.*[69] The agency undertakes regular checks at the end of each accreditation period, but also monitors ongoing compliance using the following mechanisms: support contacts, review audits and spot checks.

Support contacts are usually 3 to 4 hour visits to a facility and their frequency and format are determined at the time of accreditation.[70] If evidence of non-compliance is found, the agency may set a timetable for improvement for the facility, require more support contacts or conduct a

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[63] The 2003-2004 agreement was governed by Victorian law and the parties were subject to the jurisdiction of the Victorian courts. Victoria Guidelines, *supra* note 49, ss. 3.2 (c)(iii), 1.1 (a); Guidelines 05-06, *supra* note 60 at 13.
[64] *HSA 1988, supra* note 30, s. 18 (a)(ii).
[65] Guidelines 05-06, *supra* note 60 at 39.
[66] Guidelines 05-06, *supra* note 60 at 40, 42. Minimum mandatory reporting requirements for Quality of Care Reports include reporting on monitoring processes, actions and outcomes in relation to infection control, falls, pressure wounds and medication errors.
[67] *Health Services (Governance and Accountability) Act 2004,* (Vic.), s. 19 [*HSGA Vic*].
[68] *Ibid.,* s. 14. When determining whether to appoint a delegate, the Minister is to consider the safety and quality of the services provided.
[69] These principles are made by the Minster pursuant to Section 96-1 of the *ACA, supra* note 28.
[70] ACSAA, *supra* note 40. They may also take the form of a one or two hour teleconference between an assessor and home management. Section 3.12, senate report.

more extensive review audit. Review audits are generally two to four day long on site assessments undertaken by a team of assessors and involve observation of and interviews with residents, management and staff. Based on the team's report, the agency then decides whether to maintain, vary or revoke a facility's accreditation period. The agency will also recommend sanctions be imposed by the Department of Health and Ageing should the facility fail to meet its set timetable for improvement. Spot checks are support contacts or review audits conducted with less than 30 minutes notice to the facility.[71] They may be targeted (when there is reasonable belief of non-compliance) or random.[72] Approximately 10 percent of homes each year will have a spot check.[73] The Agency is required by the Department to visit each home at least once a year.[74]

The Senate Inquiry into aged care held that spot checks are an important method to ensure compliance and that the current system of spot checks is inadequate. It recommended that all facilities should receive a minimum of one spot check each year.[75]

Under the Victorian *Health Services Act 1988,* the boards of public health services are responsible for monitoring the performance of their public health service to ensure that:

- effective and accountable risk management systems are in place;
- effective and accountable systems to monitor and improve the quality of health services are in place;
- problems identified with the quality or effectiveness of their health service are addressed in a timely manner;
- the service continuously strives to improve the quality of the health services it provides;
- a quality committee is established.[76]

The DHS also has a performance monitoring role. The Secretary of the Department of Human Services may monitor publicly funded health services, develop criteria to make their performance comparable, and collect and analyze data.[77]

In Victoria, one aspect of the DHS' monitoring process is the patient satisfaction survey. The Patient Satisfaction Monitor commenced in Victorian acute hospitals in October 2000 for a three

[71] Senate Report, *supra* note 38, s. 3.14.
[72] ACSAA, *supra* note 40, "For Homes".
[73] Senate Report, *supra* note 38, s. 3.67.
[74] Senate Report, *supra* note 38, s. 3.15.
[75] Senate Report, *supra* note 38, s. 3.74.
[76] *HSA 1988, supra* note 30, s. 65S. The Act itself does not specify the role of Quality Committees. By-laws for the Royal Children's Hospital indicate the Board can specify functions for the Quality Committee, but its functions must include ensuring a comprehensive quality plan is in place and regularly reviewed, investigating and recommending actions for achieving best practice quality systems and receiving aggregate data necessary to fulfill its functions. *Bylaws of the Royal Children's Hospital,* (Vic.) at 8-9, Schedule C (Victoria Government Gazette S159 30 June 2004). The Victorian Quality Council states the quality committee "takes an active safety and quality planning, monitoring and evaluation role on behalf of the board." Austl., Victoria, Metropolitan Health and Aged Care Services Division, The Victorian Quality Council, *Better Quality, Better Health Care* (Victorian Quality Council Secretariat, 2003) at 45.
[77] *HSA 1988, supra* note 30, s. 11A.

year period. It provides regular ongoing monitoring and reporting patient satisfaction in 95 hospitals in Victoria. The specific objectives are:

- to determine the indices of patient satisfaction amongst patients with the key aspects of service delivery
- identify and report on the perceived strengths and weaknesses of the health care services provided to patients in Victorian public hospitals
- provide hospitals with information to inform their quality improvement initiatives with respect to service provision for patients
- set benchmarks and develop comparative data to allow hospitals to measure their performance in providing care to patients against other like hospitals.[78]

All hospitals receive comparative data and statewide results are contained in an annual report which is publicly released. Training workshops are held to assist quality managers to use the data. Participating hospitals are required to provide feedback on what action has been taken in regard to the results, especially whether the results enabled hospitals to identify trends in particular areas of service provision and to implement strategies to improve the quality of care and services provided.

The DHS also receives reports on hospital performance in relation to sentinel events, hospital acquired infections, certain elements of hospitals' clinical risk management programs, quality and safety indicators agreed upon in the Statement of Priorities and maternal, perinatal, anesthetic mortality data.[79] The Department actively monitors hospital-acquired infections and sentinel events.[80]

The Victorian Auditor General's report on patient safety discussed a number of issues related to the effectiveness of patient safety performance monitoring and reporting in Victoria. It noted that performance monitoring in health services and hospitals is highly variable, as is the quality and detail of clinical risk management data provided to boards by hospitals.[81] Without quality data, boards cannot be sure they are meeting their monitoring responsibilities and the report found few hospitals had effective systems in place for reporting such data to boards.[82] Due to variable incident classification and reporting systems in hospitals, Victoria lacks a state-level picture of its performance in relation to patient safety and the report recommends that the DHS take the lead in developing systematic information based on consistent definitions, minimum datasets, standards, performance review criteria and information management systems.[83] In its overall conclusions, the report stated that given the broad parameters in the legislation for the operation of clinical risk managements programs, the worst performers may need more

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[78] Austl., Victoria, Victorian Government Health Information, "Victorian Patient Satisfaction Monitor", online: <http://www.health.vic.gov.au/patsat/>.
[79] AG Report, *supra* note 49 at 75-78.
[80] AG Report, *supra* note 49 at 19. See the Adverse event reporting systems section for more information on the sentinel events reporting process.
[81] AG Report, *supra* note 49 at 81, 70.
[82] AG Report, *supra* note 49 at 69, 71. It also found that statewide, only 58% of hospitals gave statistical clinical risk management reports on a regular basis to their board (at 70).
[83] AG Report, *supra* note 49 at 83.

prescriptive guidelines.[84] The response of the DHS to the report noted that the DHS provides "policy and direction but not hands-on monitoring of clinical risk management."[85]

Working Conditions Regulation

The Commonwealth aged care Accreditation Standards link staffing levels and skills mix to quality of care. Although the standards do not set minimum staffing levels for aged care facilities, they do require that there are "appropriately skilled and qualified staff sufficient to ensure that services are delivered in accordance with these standards."[86] Additional standards concerning the health and personal care of residents state that residents are to receive "appropriate clinical care" and their specialized nursing needs should be "identified and met by appropriately qualified nursing staff."[87] The Senate inquiry into aged care heard evidence that indicated greater regulation of staffing levels and skills mix in aged care facilities could improve quality of care.[88] The inquiry recommended that the Aged Care Standards and Accreditation Agency undertake a consultation process with the aged care sector and consumers to develop a flexible benchmark of care that links staffing levels, skills mix and resident outcomes.[89]

In the State of Victoria, minimum nurse patient ratios are mandatory for public sector health care facilities due to certified industrial agreements reached with the Health Services Union of Australia and the Australian Nursing Federation (ANF).[90] The required ratios vary with the type of ward and the time of the shift and ratios do not apply to certain wards and units.[91] The ratios can be increased to meet patient care needs, but not decreased.[92] In general medical/surgical wards, the ratios are applied based on the actual patient numbers in a ward.[93] It does not appear that research has been done that looks at the impact of the Victorian ratios on patient outcomes in terms of patient safety.[94]

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[84] AG Report, *supra* note 49 at 3.
[85] AG Report, *supra* note 49 at 10. Their response also indicated that the more hands-on directive approach recommended in the report goes beyond its current approach.
[86] *Quality of Care, supra* note 37, Schedule 2, s. 1.6.
[87] *Quality of Care, supra* note 37, Schedule 2, ss. 2.4, 2.5.
[88] They cite a US Congressional report on establishing minimum staffing ratios in US nursing homes that concluded strong evidence supported the link between increased nurse staffing ratios and the avoidance of critical quality of care problems, although above certain thresholds staffing increases did not improve quality. Austl., Commonwealth, Senate, *Quality and Equity in Aged Care* (Canberraa: Senate Printing Unit, 2005) at s. 3.82, online: <http://www.aph.gov.au/senate/committee/clac_ctte/aged_care04/report/report.pdf> [Senate Inquiry]. Senate inquiry into aged care, citing US Department of Health & Human Services, Report to Congress: Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes, December 2001, ss. 1.19-1.20.
[89] *Ibid.,* ss. 3.91-3.93.
[90] "Nurses (Victoria Public Health Sector) Multi Business Agreement 2004-2007", online: Victorian Government Health Information <http://www.health.vic.gov.au/nursing/ir/index.htm> [Nurses Agreement 04-07]. Nurses (Victorian Public Health Sector) Multi-Employer Agreement 2000-2004.
[91] Nurses Agreement 04-07, *ibid.,* s. 1 (d), Schedule C.
[92] Australian Nursing Federation, "5200 more reasons to commit to nurse patient ratios", ANF media release, (12 Oct 2004), online: < http://www.anfvic.asn.au> [ANF].
[93] Nurses Agreement 04-07, *supra* note 90, Schedule C.
[94] ANF, *supra* note 92. A report conducted by the University of Sydney's workplace research centre and commissioned by the ANF looked at working conditions for nurses after the ratios. It surveyed ANF Victorian branch public sector nurses. Nurses with ratios and in the same work area for 3 years who indicated quality of care

Actors in the health sector in Australia have identified lengthy hours of work as a safety issue in Australia.[95] However, to date initiatives in regard to workplace hours have been dominated by the professional bodies, in particular the Australian Medical Association. The AMA developed the *National Code of Practice – Hours of Work, Shift-work and Rostering for Hospital Doctors*.[96] It is a voluntary Code that was developed as part of an extensive consultative process with institutions, health care administrators, doctors and other interested parties. It is consistent with OSH requirements in the states and territories in Australia.

Professional Regulation

Professional regulation is a function of the states and territories under section 51 of the *Constitution*. However, state authority is somewhat limited by the *Mutual Recognition Agreement* (1993) (*Commonwealth Mutual Recognition Act 1992*) between all states and territories and the *Trans Tasman Mutual Recognition Agreement* between Australia and New Zealand (1998) (*Trans Tasman Mutual Recognition Act 1997*). These agreements require mutual recognition of health professional qualifications. Since 1992, Australian jurisdictions have worked together to develop a common approach to the regulation of health professions in order to reduce unnecessary regulation, to achieve labour force flexibility and to create an integrated market where goods, services, and service providers flow freely.

The *National Competition Policy* is a 1995 agreement between the Commonwealth, States and Territories to establish a national approach to competition policy and to remove anti-competition provisions unless there is a demonstrable net public benefit. Professional regulation must therefore be scrutinized for its impact upon competition and if it does impact upon competition, then justifications must be provided.

The Australian Health Ministers Advisory Council (AHMAC) also has a role in professional regulation. It agreed on those professions which should continue to be regulated via statute and established a process to assess the need for regulation of professions that are regulated in some states and not in others. The Advisory Council has no power to enforce its recommendations.

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would be worse without the ratios (32%of total survey population) indicated that the ratios had improved patient care because they allowed more time for the personal care of patients, made it easier to manage workloads and gave more time for completing documentation. John Buchanan & Gillian Considine, “Combating work intensification: Do Nurse-patient ratios reduce workloads in Australian Public Hospitals”, A Paper prepared for the 23rd International Labour Process Conference, University of Strathclyde, Glasgow, 21 – 23rd March 2005 at 15, online: <http://www.hrm.strath.ac.uk/ILPC/2005/papers/buchanan-considine.pdf>.

[95] The Australian Resource Centre for Hospital Innovations, “Safe Staffing and Patient Safety Literature Review” (Canberra: The Australian Council for Quality and Safety in Health Care, 2003), online: <http://www.archi.net.au/content/index.phtml/itemId/45034>.

[96] Australian Medical Association, *National Code of Practice – Hours of Work, Shift-work and Rostering for Hospital Doctors,* (Kingston: AMA, 2005) online: AMA <http://www.ama.com.au/web.nsf/doc/WEEN-5Q47JC/$file/Nat%20Code%20of%20Practice.pdf>.

In 2004, the Australian Health Minister's Conference agreed to establish a single national system for medical registration, rather than the current system that varies between the states.[97] Important elements of the nationally consistent approach to medical registration include common categories of registration, a national registration database, legislatively defined public access to medical register information and greater emphasis on the maintenance of professional competency.[98] A legislation working group is currently developing drafting instructions for nationally consistent medical registration legislation.[99]

The State of Victoria currently has 12 regulatory boards for various health professions, which are governed by separate pieces of legislation.[100] The registration Acts focus on the reservation of title to those who are registered members of the profession, with risky and intrusive practices regulated through other legislation (e.g. drugs and poisons Acts).[101] The primary purpose of each statute is the protection of the public.

The legislation creates registration boards, barriers to entry to the profession by untrained persons, consumer complaints mechanisms, and mechanisms for establishing training and practice requirements and enforcing them. Common powers and rules in relation to registration, complaints and discipline processes are achieved through a number of standard provisions throughout the Acts.[102] For example, there is a standard definition of unprofessional conduct in all the registration Acts and standard powers for boards to address cases of false advertising. However, there is also variability between the Acts. Only certain boards, such as the Medical Practitioners Board and the Pharmacy Board, have the power to conduct performance assessments and reviews.[103]

Members of the boards are appointed by the Governor in Council. With the exception of Medical Radiation Technologists Board, they are independent, self-funding statutory authorities.[104] All boards have legal and community members.[105]

The *Medical Practice Act 1994* sets out the legislative framework for the regulation of medical practitioners in Victoria and provides a model for the Victorian system.[106] In addition to

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[97] Austl., Commonwealth, "Australian Health Ministers agree on nationally consistent approach to medical registration", Joint Communique, April 23 2004, online: Department of Health and Aging < www.health.gov.au>.

[98] Medical Practitioners Board of Victoria, "Nationally Consistent Approach to Medical Registration" (March 2005) 1 Bulletin 4.

[99] Health Workforce Australia "Current Projects", online: <http://www.health.nsw.gov.au/amwac/projects.html>.

[100] There are 11 profession-specific Acts in Victoria. The Medical Radiation Technologist Board is governed by the *Health (Medical Radiation Technologists) Regulations 1997,* (Vic.), and was established under the *Health Act 1958,* (Vic.) [*HA*]. Victoria is the only state/territory in Australia to regulate the practice of Chinese Medicine.

[101] Austl., Victoria, Department of Human Services, *Regulation of the Health Profession in Victoria: A Discussion Paper* (Melbourne: Department of Human Services, 2003) at 20 [*Discussion Paper*].

[102] Austl., Victoria, Department of Human Services, *Review of the Regulation of the Health Professions in Victoria: Options for Structural and Legislative Reform* (Melhourne: Department of Human Services, 2005) at 2 [*Review*]. See also *Discussion Paper*, *ibid.* at 23.

[103] *Review*, *ibid.* at 23.

[104] Austl., Victoria, Department of Human Services, "Registration Boards", online: <http://www.dhs.vic.gov.au/pdpd/workforce/pracreg/reg_boards.htm>. Discussion Paper, *supra* note 101 at 23.

[105] *Discussion Paper*, *supra* note 101 at 23.

registration, the Board's responsibilities under the Act include investigating concerns about a practitioner's professional conduct, performance or fitness to practice, regulating standards of medical practice in the public interest, and advising the Minister of concerns about the health system that arise out of the Boards' work.[107] When the Board receives a notification,[108] the Board must first discuss it with the Victorian Health Services Commissioner (HSC) to determine which is the appropriate body to deal with the notification.[109] If the notification is within the Board's jurisdiction, is not frivolous or vexatious and is not being dealt with by the HSC, then the Board must conduct a preliminary investigation.[110] At the end of this investigation, the Board can choose to:

- close the investigation if there is insufficient evidence;
- refer the doctor for a medical examination;
- have the practitioner's performance assessed by a practitioner or reviewed by a panel;
- refer the case to an informal hearing if it believes that the practitioner has engaged in unprofessional conduct not a serious nature; or
- refer the case a formal hearing if it believes that the practitioner has engaged in unprofessional conduct of a serious nature.[111]

The Board can suspend a practitioner's registration at any time if it believes there is a serious risk to the health and safety of the public.[112] Members of the Board who are involved in the preliminary investigations cannot sit on a hearing or review panel.[113] Formal hearings are open to the public, while performance reviews and informal hearings are not.[114] In the case of informal and formal hearings, the notifier (or complainant) is to be told by the Board of the findings and the reasoning behind them within 28 days of a decision.[115] The Board must notify various bodies, such as the HSC, the employer and the registration authorities of other states, if it imposes conditions on, suspends or cancels a practitioner's registration.[116] Certain Board decisions can be appealed to the Victorian Civil and Administrative Tribunal and their administrative actions are subject to review by the Victorian Ombudsman.[117] The Board publishes formal hearing cases and de-identified summaries of informal hearings in their quarterly bulletin and in their annual report to Parliament.

Medical practitioners are required under the Act to report the ill-health of a registered health practitioner they are treating to the appropriate board when that illness has seriously impaired the

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[106] *Discussion Paper, supra* note 101 at 23.
[107] *Medical Practice Act 1994,* (Vic.), s. 66 [*MPA*].
[108] The *Health Practitioner Acts (Further Amendments) Act 2002* replaced the concept of complaint with that of notification. Medical Practitioners Board of Victoria, *Annual Report 2003* (Melbourne, 2004) at 30 [MPB 2003].
[109] *MPA, supra* note 107, s. 23(2). The Comissioner handles matters suitable for conciliation, while the Boards deals with matters relating to unprofessional conduct. MPB 2003, *ibid.* at 15.
[110] *MPA, supra* note 107, s. 25.
[111] *MPA, supra* note 107*, ss.*38K, 43, 45A; MPB 2003, *supra* note 108 at 16-17.
[112] *MPA, supra* note 107, s. 27.
[113] *MPA, supra* note 107, ss. 47, 40, 38F.
[114] *MPA, supra* note 107, ss. 49, 38G, 42.
[115] *MPA, supra* note 107, s. 57.
[116] *MPA, supra* note 107, s. 57.
[117] *MPA, supra* note 107, s. 60; *Review, supra* note 102.

health practitioner's ability to practice and may put the public at risk.[118] They do not attract any civil or criminal liability if the report is made in good faith.

Victoria has recently reviewed the way in which it regulates health professionals. The Review's goals were:

- to ensure an updated and responsive regulatory framework exists that equips boards to protect the public;
- to promote public confidence in the framework;
- to ensure good links between practitioner quality mechanisms and health system quality mechanisms; and
- to promote administrative and technical efficiency in the scheme.[119]

The following principles were used as the basis for the review: accountability, transparency, fairness, effectiveness, efficiency, flexibility and consistency. In April 2005, a review paper identifying problems with the current system and a variety of reform proposals was released.[120] Key findings about the system included:

- there is poor separation of powers in the disciplinary process, particularly between the investigation/prosecution and hearing/determination functions;
- the legislative framework is cumbersome and inefficient due to the time and resources needed to amend all the Acts to reflect current practice, which leaves some boards without the all powers they need to protect the public;
- some consumers lack confidence in the transparency and fairness of the complaints process; and
- the model does not do enough to link practitioner quality with system quality.[121]

The paper presented five main options for structural reform to address the above concerns, which included transferring the preliminary investigative function to another body, creating internal and external rights of review for complainants or establishing a separate health professions disciplinary tribunal (this last option was seen to be consistent with interstate and international trends). The Review held that establishing a single health professions council, modeled after the United Kingdom's Health Professions Council, would improve consistency, and could improve transparency, procedural fairness, and consumer confidence in the independence of the system.[122]

In late 2005, the Victorian Parliament passed the *Health Practitioners Registration Act 2005*.[123] This Act is not yet in force. Its purpose is to:

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[118] *MPA, supra* note 107, s. 37.
[119] *Review, supra* note 102 at 1.
[120] The review began in 2002 and a discussion paper and a study of complainants' experiences with the Boards were also made public. They are available on the DHS webpage: <http://www.dhs.vic.gov.au/pdpd/workforce/pracreg/sys_review.htm>.
[121] *Review, supra* note 102 at 2-3.
[122] *Review, supra* note 102 at 13.
[123] *Health Practitioners Registration Act 2005* (Vic.) [*HPRA 2005*].

- protect the public by providing for the registration of health practitioners and a common system of investigations into professional conduct, professional performance and the ability to practice of registered health practitioners
- protect the public by providing for registration and investigations of students
- establish or continue the existence of the individual boards responsible for registration of health practitioners
- provide for the regulation of pharmacies and associated facilities

The Boards now are responsible for registering and granting certification of registrations to health practitioners and students. Boards continue to be responsible for investigating matters that are brought to its attention, unless the Health Services Commissioner is dealing with the matter, it is frivolous, vexatious, lacking in substance, does not warrant investigation, the practitioner or student is no longer registered or the matter is referred directly to a health or hearing panel. A practitioner/student can be required to undergo a health or performance assessment if they refuse to undertake such an assessment. If the matter is to proceed, the Board establishes a professional standards panel hearing. If, after the hearing, the panel is satisfied that there may be a finding of unprofessional conduct, professional misconduct, or unsatisfactory professional performance the panel may:

- refer the matter to the Victorian Civil and Administrative Tribunal (VCAT) or a health panel for further action;
- reprimand;
- order counseling;
- place conditions on registration;
- order the practitioner to alter his/her practice; or
- undertake further education or training.

The Panel must refer apparent professional misconduct or cases where the ability to practice is so much in doubt that cancellation of registration must be warranted. If, after a formal hearing, VCAT determines a sanction is warranted, it has a variety of sanctions available, including leveling a maximum $50,000 fine.

Practitioners must inform the appropriate board if a court has ordered that the practitioner pay damages or compensation within 30 days of the order.[124] Practitioners also must report practitioners or students to whom they are providing treatment if the illness or condition they are treating impairs the ability of the practitioner/student's ability to practice and may place the public at risk. Practitioners are immune from civil or criminal liability if they report in good faith.

Products Regulation

The regulation of therapeutic products in Australia is undertaken at the federal level. A unit of the Department of Health and Aging, the Therapeutic Goods Administration (TGA) is the agency

[124] *Ibid.,* s. 34.

that evaluates the quality, safety and efficacy of medicines and medical devices prior to use in Australia, while providing timely access for consumers.[125] They manage the risks associated with therapeutic goods through:

- auditing and assessment of manufacturing process for quality purposes;
- pre-market assessment of goods; and
- post-market surveillance and monitoring of compliance with standards.[126]

The TGA administers the *Therapeutic Goods Act 1989,* and associated regulations and orders. Since 1998, the TGA has been required by Government to operate on a full cost recovery basis through the collection of fees and charges from industry. [127]

The legislation establishes a risk management based regulatory framework. Unless subject to a legislative exemption, all products for which therapeutic claims are made must be either listed or registered in the Australian Register of Therapeutic Goods (ARTG) before they can be legally supplied in Australia. [128] The level of regulatory scrutiny a product undergoes in order to be included in the Register depends on the level of risk it poses.

In the case of medicines, higher risk medicines (prescription medicines, some non-prescription medicines) are classified as "registrable" and are evaluated for safety, quality and efficacy using a detailed pre-market assessment process.[129] Lower risk medicines (most complementary medicines) are "listed" and assessed for safety and quality, but not efficacy.[130] Sponsors can self-assess their products for listing in certain situations. A medicine's risk is assessed using factors such as toxicity and strength, side effects, and the seriousness of illness being treated.[131] The *Therapeutic Goods Regulations 1990* sets out classes of products that must be registered or listed.[132]

Australian manufacturers of medicines, regardless of whether their medicines are listed, registered or exempt, must be licensed. In order to obtain a license, they must comply with the Code of Good Manufacturing Practice (GMP), a set of manufacturing principles and procedures used internationally to ensure the medicines produced are safe and of a consistently high quality.[133]

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[125] Austl., Commonwealth, Department of Health and Aging Therapeutic Goods Administration, *Medicines Regulation and the TGA* (September 2004) at 1, online: TGA <http://www.tga.gov.au/docs/pdf/medregs.pdf> [*Medicine Regulation*]; Austl., Commonwealth, Department of Health and Aging Therapeutic Goods Administration, *The Therapeutic Goods Administration's risk management approach to the regulation of therapeutic goods,* (Version 1 of July 2004) at 10, online: TGA <http://www.tga.gov.au/about/tgariskmnt.pdf> [*TGA Risk Management*].

[126] Austl., Commonwealth, Department of Health and Aging Therapeutic Goods Administration "Regulation of Therapeutic Goods in Australia," online: TGA <http://www.tga.gov.au/docs/html/tga/tgaginfo.htm> [Regulation].

[127] *Medicines Regulation, supra* note 125 at 1-2.

[128] *TGA Risk Management, supra* note 125 at 4.

[129] *Medicines Regulation, supra* note 125 at 5; *TGA Risk Management, supra* note 125 at 13.

[130] *Medicines Regulation, supra* note 125 at 5.

[131] Regulation, *supra* note 126.

[132] *Therapeutic Goods Regulations 1990,* (Cth.), Schedule 3, 4 [*TGA Regs*].

[133] *Therapeutic Goods Act 1989,* (Cth.), Part 3-3 [*TGA*]*; TGA Risk Management, supra* note 125 at 17-18.

A new regulatory system for medical devices was introduced in 2002 based on the Global Harmonization Task Force (GHTF) model.[134] The system was designed to reflect accepted best practices in regards to safety, quality and risk management and to provide enhanced regulatory flexibility and capacity in relation to new technologies.[135] Mandatory essential principles set out the safety and performance requirements for all medical devices.[136] Essential principles include the following:

- the use of the medical device must not compromise health and safety;
- the design and construction of medical devices must conform with safety principles;
- a device must be designed and produced in a way that addresses long term safety;
- medical devices should be suitable for their intended purpose; and
- the benefits of medical device use are to outweigh any side effects.[137]

The principles themselves do not specify the standards to be used for compliance purposes. Medical device standards that conform to the essential principles are published as orders in the *Commonwealth Gazette*. However, the use of these standards is voluntary and manufacturers are free to use other standards to demonstrate conformance. However, the use of other standards will not lead to a presumption of compliance.[138]

Medical devices are classified according to risk, and their classification determines the type of conformity assessment procedures a manufacturer can choose from to demonstrate compliance with the relevant essential principles. [139] For some lower risk devices, manufacturers may choose to self-certify their device, while for higher risk devices, manufacturers may choose to implement a full quality management system to be assessed by the TGA or to have their device undergo type testing by the TGA.[140] Once again, the use of gazetted conformity assessment standards is voluntary, but if they are used, the manufacturer is deemed compliant.[141] Medical devices must be manufactured under a quality system appropriate for their classification.[142] Having classified the device and chosen an appropriate conformity assessment procedure, the manufacturer then signs a declaration of conformity. The role of the TGA, or an overseas body where acceptable, is to certify that the appropriate conformity assessment procedures are in place, but the level of intervention used by the TGA to do so depends on the device's class.[143] Subject to legislative exemptions, all Australian manufacturers of devices and overseas manufacturers of certain devices must hold a conformity assessment certificate from the TGA

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[134] The legislative basis for the system is the *TGA 1989, ibid,.* as amended by the *Therapeutic Goods Amendment (Medical Devices) Bill 2002,* and the *Therapeutic Goods (Medical Devices) Regulations 2002,* (Cth.) [*TGMD Regs*].
[135] Austl., Commonwealth, Therapeutic Goods Administration, *Australian Medical Devices Guidelines,* (Woden: Medical Devices Information Unit, 2003) at 6 [*Devices Guidelines*].
[136] *TGMD Regs, supra* note 134, Schedule 1.
[137] *TGMD Regs, supra* note 134, Part 1, Schedule 1.
[138] *Devices Guidelines, supra* note 134 at 7.
[139] Siepie Larkin, Presentation, Office of Devices, Blood and Tissues, TGA; *TGA Risk Management, supra* note 125.
[140] *The Therapeutic Goods Administration's risk management approach to the regulation of therapeutic goods,* Version 1 of July 2004, page 24, TGA webpage, online at <www.tga.gov.au>
[141] Larkin, *ibid.*
[142] Austl., Commonwealth, National Coordinating Committee on Therapeutic goods, *Reducing the public health risks associated with reusable medical devices*, (Woden: TGA Publications Office, May 2004) at 3 [*Reducing public health risks*].
[143] *Devices Guidelines, supra* note 135 at 10-11.

before they can apply to register their product on the ARTG.[144] As a further level of risk assessment, the TGA is required by law to audit certain high risk applications and may audit any other application it selects.[145]

Sponsors and manufacturers of medicines and medical devices have adverse event reporting obligations under the legislation. Section 29 of the Act requires sponsors to inform the TGA in writing as soon as they become of aware of information indicating their registered or listed medicines are having adverse effects. Sponsors of registered medicines regulated by the Drug Safety and Evaluation Branch must report serious unexpected and expected individual adverse drug reactions immediately and no later than 15 calendar days.[146] When a sponsor identifies a significant safety issue based on foreign data or an action is taken by foreign regulators, the sponsor must notify the TGA within 72 hours.[147] Sponsors of medical devices must report the following adverse events:

- events that represent a serious threat to public health must be reported within 48 hours;
- events that led to the death or serious deterioration of health of either patients or users must be reported within 10 days; and
- events which might lead to the death or serious deterioration of health of either patients or users must be reported within 30 days (near adverse events).[148]

The Adverse Drug Reactions Unit operates a voluntary system of adverse events reporting by health professional and consumers. The reports are entered into a national database and assessed by health professionals. Reports involving serious reactions, vaccines and complementary medicines are forwarded to an expert committee, the Adverse Drug Reactions Advisory Committee (ADRAC), for further evaluation.[149] The Committee issues a quarterly bulletin and may advise providers/consumers of problems, recommend re-labeling, request further studies, and recommend restrictions for or removal of the drug. The TGA Incident Report Investigation Scheme (IRIS) receives voluntary adverse event reports associated with medical device use from health professionals and patients.[150] Reports are assessed initially by the coordinator, who can decide to investigate serious problems at that time. All reports are entered into a database and assessed by an expert panel, who decides on the appropriate level of investigation. Outcomes of the investigation may include recalls, safety alerts, compliance testing, or articles in the TGA news.

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[144] *TGMD Regs, supra* note 134, Part 4, 4.1*; TGA Risk Management, supra* note 125 at 25.
[145] *TGA, supra* note 133, s. 41FH*; TGMD Regs, supra* note 134, Part 5, 5.3.
[146] *Therapeutic Goods Regulations 1990,* s. 15A, requires sponsors to comply with the reporting requirements in the "*Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines regulated by the Drug Safety and Evaluation Branch*"; Austl., Commonwealth, Therapeutic Goods Administration, *Australian Guideline for Pharmacovigilance Responsibilities of Sponsors of Registered Medicines regulated by the Drug Safety and Evaluation Branch,* (Woden: TGA, 2003) at 7-8 [*Pharmaco*].
[147] *Pharmaco*, *ibid. at* 8.
[148] *TGMD Regs, supra* note 134, s. 5.7; *Devices Guidelines, supra* note 135 at 16.
[149] Austl., Commonwealth, Therapeutic Goods Administration, "Adverse Drug Reactions, what happens to a report", online: TGA <http://www.tga.gov.au/adr/rephap.htm>.
[150] *Reducing public health risks, supra* note 142 at 30-31.

In December of 2003, the Australian and New Zealand governments agreed to establish a joint regulatory agency for therapeutic products, which is expected to be operational by July 2006. [151]

Inquiry Processes

In the past six years, a number of state and territorial governments have initiated health care inquiries in response to safety and quality concerns.[152] These inquiries were or are being conducted by either a statutory commission of inquiry or by the state or territory's health care complaints body. Charged with identifying clinical and administrative issues that may have contributed to adverse patient outcomes over a 10 year period, the King Edward Memorial Hospital (Obstetrics & Gynaecological Services) Inquiry in Western Australia focused primarily on organizational and systems issues at the Hospital that most affected patient safety and quality.[153] The effectiveness of these inquiries as a mechanism for change does not appear to have been systematically studied.[154]

In Victoria, under the *Health Services Act 1988*, the Secretary of the Department of Human Services may initiate an inquiry into any matter arising in the performance of his functions, such as encouraging safety and quality improvement or monitoring and evaluating publicly funded health services.[155] The Minister may also refer matters to the Health Services Commissioner for an inquiry or the Commissioner may initiate an inquiry into "broader issues of health care arising out of complaints received" with Ministerial approval.[156] The Commissioner conducted a 3

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[151] See the New Zealand Products Regulation section for more detail.

[152] Austl., W.A., "Inquiry into obstetric and gynecological services at King Edward Memorial Hospital 1990-2000, Final Report" (November 2001) online: <http://ww2.slp.wa.gov.au/publications/publications.nsf>; Bret Walker, "Final Report on the Special Commission of Inquiry into the Campbelltown and Camden Hospitals, 2004" (New South Wales, 2004); Austl., A.C.T., Community & Health Services Complaints Commissioner, "A Final Report of the Investigation into Adverse patient outcomes of Neurosurgical Services provided by the Canberra Hospital" (February 2003), online: <http://www.health.act.gov.au/c/health?a=sendfile&ft=p&fid=1070950146&sid=>; Austl., Victoria, Health Services Commissioner) "Royal Melbourne Hospital Inquiry Report" (August 2002), online: <http://www.health.vic.gov.au/hsc/papers.htm>; Austl., Qld., "Queensland Public Hospitals Commission of Inquiry"online: < http://www.qphci.qld.gov.au/default.htm>. Austl., Qld, "Queensland Health Systems Review" online: <http://www.healthreview.com.au/>. See also Thomas A. Faunce & Stephen NC Bolsin, "Three Australian whistleblowing sagas: lessons for internal and external regulation" 181:1 MJA 44, online: <www.mja.com.au>.

[153] Austl., W.A., "Abstact, Volume 1 Inquiry into obstetric and gynecological services at King Edward Memorial Hospital 1990-2000, Final Report" (November 2001), online: <http://ww2.slp.wa.gov.au/publications/publications.nsf/Inquiries+and+Commissions>. The Inquiry's 237 recommendations were given to an Implementation group, who determined what changes were needed for compliance. All but 4 recommendations requiring legislative action were held by the Implementation group to be satisfactorily addressed. 43 of the recommendations were determined to require ongoing audit by the hospital. The Department of Health was to conduct an independent implementation audit. KEMH Inquiry, online: <http://www.health.wa.gov.au/kemhinquiry>.

[154] Norman Swan, "The Health Report: Health Care Inquiries" *ABC News* (June 20, 2005), Program Transcript, online: <http://abc.net.au/rn/talks/8.30/helthrpt/stories/s1396044.htm>.

[155] *HSA 1988, supra* note 30, ss. 144 (1), 11A.

[156] *Health Services (Conciliation and Review) Act 1987,* (Vic.), ss. 9 (1) (l), 9 (1) (m) [*HSCRA*].

month long inquiry, which focused on organizational and systems issues, into an incident at the Royal Melbourne Hospital (RMH) at the request of the Minister in 2002. [157]

Each Australian state and territory has legislation that governs coroners. Having recognized the potential of coronial findings to improve health care safety, the Australian Council on for Safety and Quality in Health Care (ACSQHC) commissioned a project to examine the role of coronial death investigation processes in reviewing the safety and quality of health care in Australia. The project was to make recommendations for improving legislative and administrative systems to ensure that coronial findings and recommendations can be used effectively for system improvement.[158] The final report was submitted in 2003, but was not made available to the public.[159]

In the state of Victoria, a parliamentary law reform committee is currently reviewing the *Coroners Act 1985* and considering whether the legislation provides an appropriate framework for preventing deaths and improving safety.[160] The Committee's discussion paper touches on a number of issues related to patient safety.[161] The paper notes that there is some indication in Australia that some doctors may not be reporting all cases of reportable deaths that happen in hospitals.[162] One possible explanation raised is a lack of understanding on the part of doctors as to when to report these deaths. Victorian doctors are required by the Act to report deaths to the coroner if they appear to have been unexpected, unnatural, violent, due to injury or accidental or if they involve anaesthetics. [163] However, two other jurisdictions, the Australian Capital Territory (ACT) and Queensland, have created specific provisions in their legislation that define with greater clarity when deaths involving medical treatment are reportable. In Queensland, for example, their Act states a death is reportable to the coroner if "the death was not reasonably

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[157] Austl., Victoria, Health Services Commissioner, Analysis of the Inquiry held by the Health Services Commissioner 2002, into an Incident at the Royal Melbourne Hospital, Victoria. (October 2004), online: <http://www.health.vic.gov.au/hsc/analysisrmh.pdf>. Undertaken to provide a road map for relevant future inquiries, the analysis states the inquiry was successful as it resulted in quality improvements at the RMH and other hospitals have used the inquiry's recommendations to audit their services. The inquiry's ability to avoid being unduly legalistic, because of the legislative framework, the Commissioner's reputation for successful conciliation and community accessibility and the full cooperation of the hospital, was seen as an important factor to its success. (at 3 and 7).

[158] The Australian Council for Safety and Quality in Health Care, *Safety Through Action: Improving Patient Safety in Australia* (2002) at 17.

[159] Joseph Ibrahim et al, "The Role of the Coronial process in initiatives for improving patient safety and quality of health care, Final report of a consultancy into the Coronial Death Investigation process in Australia: its role In reviewing the safety and quality of health care provision. 2003, Report submitted to the Australian Council for Safety and Quality in Health Care, Commonwealth Department of Health and Ageing, Canberra. (Confidential Report). VIFM website, online at: <http://www.vifm.org/in_research_pubs.html>. A discussion of the potential benefits and limitations of information from coronial investigations initially identified by the project can be found in the following presentation: Joseph Ibrahim, "The Coroner, Safety and Health Care: Integrating the Coroner's investigation process into initiatives for improving safety and quality in health care" (Paper presented at the First Australian Conference on Safety and Quality in Health care: Safety and Quality in Action, Perth, Western Australia, 16 July 2003). Online at: <http:www.aaqhc.org.au/pdf/resources/2003_ibrahim.pdf>

[160] Austl., Victoria, "Inquiry into the *Review of the Coroner's Act 1985*, Terms of Reference" (2004), online: http://www.parliament.vic.gov.au/lawreform/Coroner/TOR.htm.

[161] Austl., Victoria, Law Reform Committee, *Coroner's Act 1985, Discussion Paper* (April 2005) [*Coroner's Discussion*].

[162] *Ibid.* at 14.

[163] *Coroners Act 1985,* (Vic.), ss. 3(1), 13(3)(a) [*CA 1985*].

expected to be the outcome of a health procedure."[164] Another contributing factor may be that the purpose for reporting is unclear and death and injury prevention and improving safety are not included in the listed purposes of the Act.[165] The discussion paper also discusses potential reforms to the death certification system in light of the Shipman case in the United Kingdom.

The Committee asks whether the coroner's current role allows for appropriate involvement in improving general patient safety in the Victorian health care system and what obstacles exist that prevent the coroner from fulfilling this role.[166] The paper mentions the viewpoint of the Victorian Clinical Liaison Service, [167] which stated one obstacle to a clearer focus on patient safety is that the health care sector is under no obligation to respond to the coroner's findings or recommendations.[168] Under the Victorian Act, a coroner may make recommendations on any matter relating to a death, including public health and safety, to any Minster or public statutory authority, but a response is not required.[169] The Victorian State Coroner's office currently sends findings to anyone who is interested or could benefit from them and patient safety related findings of public interest are posted on their website.[170] Options for reform include improved administrative and legislative arrangements for information sharing between health departments, health care professionals and coroners.[171] The paper notes that there has been no systematic review to date of the impact of coronial findings in the health system and their effectiveness in improving hospital patient safety.[172]

The Victorian Act gives the State Coroner discretionary power to give directions to coroners about investigations and how to conduct them.[173] After a multidisciplinary process that included policy makers and health service providers, an investigation standard for fall-related deaths that occur in public and private hospitals and nursing homes was developed.[174]

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[164] *Coroners Act 2003,* (Qld.), s. 8(3)(d) [*CA 2003*]: Schedule 2 of the Act defines a health procedure as " a dental, medical, surgical or other health related procedure, including for example the administration of an anaesthetic,analgesic,sedative or other drug." Guidelines issued by the Queensland State Coroner provide further assistance. See *Coroner's Discussion, supra* note 161 at 13.

[165] Austl., Victoria, Australian Council for Safety and Quality in Health Care (ACSQHC), Page 2, Submission Number 51 to the Inquiry into the Review of the Coroner's Act 1985, Victorian Parliament Law Reform Committee, online: <http://www.parliament.vic.gov.au/lawreform/>

[166] *Coroner's Discussion*, *supra* note 161 at 78.

[167] The Victorian Clinical Liaison Service is an initiative of the State Coroners Office and the Victorian Institute of Forensic Medicine (VIFM). The Service is a team of clinicians who assist coroners in investigating adverse events and look for trends in cases in order to identify systems issues. They distribute a quarterly newsletter of cases identifying adverse events resulting from system failures for interested clinicians and those involved in healthcare governance. Clinical Liaison Service, online: VIFM <http://www.vifm.org/clinical_liaison.html>

[168] *Coroner's Discussion, supra* note 161 at 74.

[169] *CA 1985,supra* note 163, *s.* 21(2); *Coroner's Discussion, supra* note 161.

[170] Austl., Victoria, The State Coroner's Office of Victoria, "Coronial findings of public interest, health, medical & hospital category", online: < http://www.coronerscourt.vic.gov.au>. An example of the coroner's role in relation to patient safety is illustrated in the cases of June Long and Cheryl Hoggins.

[171] *Coroner's Discussion, supra* note 161 at 75.

[172] *Coroner's Discussion, supra* note 161 at 72.

[173] *CA 1985, supra* note 163, s. 16.

[174] Victorian Institute of Forensic Medicine, "Investigation of Fall-Related Deaths in Hospitals", online: <http://www.vifm.org/inclsfalls2.html>.

The first of its kind in the world, the National Coroners Information System (NCIS) is a database that contains information, such as the medical cause of death and the circumstances surrounding a death, from all Australian coroners' cases since 2000.[175] Information from the system has been used in the context of patient safety in areas such as deaths associated with pregnancy, the insertion of naso-gastric tubes and the administration of medication in nursing homes.[176] It is funded by a number of Commonwealth and state agencies. Although not created by statute, NCIS is recognized by the coroners' legislation in Queensland.[177]

Compensation Systems

Australia has a common law system where claims in respect of medical malpractice are settled through the tort system. Australia has recently experienced a dramatic increase in medical indemnity claims and the size of awards.[178] Doctors, in particular obstetricians and those practicing in rural areas, are said to have left the profession as medical indemnity premiums increased substantially.[179] Private medical indemnity schemes exited the Australian market, went bankrupt or into provisional liquidation in 2002, prompting doctors to threaten to walk away from their jobs unless government provided assistance.[180] An arrangement was worked out where the Commonwealth government guaranteed insurance provided by United Medical Protection (UNP/AMIL), Australia's largest medical indemnity insurer, allowing them to recover from near collapse.[181] The Commonwealth government also legislated a number of financial schemes to help ensure the continuation of the medical indemnity insurance market.[182]

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[175] *Coroner's Discussion, supra* note 161 at 67.

[176] Victorian Institute of Forensic Medicine, "The National Coroners Information System" (November 2004) 2:4 Coronial Communique 2, online: http://www.vifm.org/attachments/o352.pdf. See also Australian Council for Safety and Quality in Health Care, "Safety in Numbers", Attachment to Safety in Practice-Making Health Care Safer, Second Report to the Australian Health Ministers Conference, (1 August 2001) at 17.

[177] *CA 2003, supra* note 164.

[178] Hon. Justice Michael Kirby, "Medical Malpractice – An International Perspective of Tort System Reforms", Speech (2000), online: High Court of Australia <http://www.hcourt.gov.au/speeches/kirbyj/kirbyj_med11sep.htm>; Austl., Commonwealth, Medical Indemnity Review Panel "Affordable, Secure and Fair: Report to the Prime Minister," (10Dec2003) at para. 3 [MIRP].

[179] Austl., Commonwealth, Australian Competition and Consumer Commission (ACCC), "Medical Indemnity Insurance - Monitoring Report, December 2003" (Dickson: ACCC Publishing, 2004) at viii [ACCC]. Average doctor premiums approximately doubled over the five year period preceding 2002-2003 and in extreme cases, medical practitioners were paying over a third of their income for coverage. MIRP, *ibid.* at 1.

[180] MIRP, *ibid. a*t para 11. Austl., Commonwealth, *Reform of liability insurance law in Australia,* (Canberra: Commonwealth Copyright Administration, 2004) at A10, online: <http://www.treasury.gov.au> [*Reform 2004*]. For a brief summary of events contributing to the medical negligence crisis, see also Minter Ellison Lawyers, "Medical Negligence – the state of the law in Australia" (July 2004) at 2, online: < http://www.minterellison.com/public/connect/internet/>.

[181] *Reform 2004, ibid.* at A10.

[182] Please see ACCC, *supra* note 179 at 12-16 for further details about the schemes and the legislation which established them.

Tort law reform was also seen as crucial for improving the medical indemnity situation.[183] In Australia, states and territories have jurisdiction over the common law, including the law of negligence, and are responsible for statutes relating to civil liability.[184] In 2002, a report reviewing the law of negligence in Australia made 61 recommendations to state and federal Ministers for principled tort law reform, which included shorter limitation periods, higher injury thresholds for compensation, caps for most categories of damages and the use of a modified "Bolam principle" test for determining the standard of care in medical practitioner negligence cases.[185] Established by the Commonwealth Government, the Medical Indemnity Policy Review Panel, which included senior members of the medical profession, released its recommendations for an affordable, secure and fair medical indemnity system in 2003, which included:

- that States fully implement the recommendations of the Review of the Law of Negligence as a matter of urgency;
- that States consider establishing medical assessment panels to determine whether doctors have acted unprofessionally before cases can go to court; and
- that all State and Territory governments implement professional standards legislation for medical professionals that includes compulsory insurance, risk management and alternative dispute resolution in return for reduced litigation exposure.[186]

State and territorial governments have implemented major reforms to tort law in the past few years, including the introduction of minimum thresholds of impairment for accessing general damages (non-economic loss: ie pain and suffering compensation), caps on damages for both economic loss (ie past/and or future income) and non-economic loss, and changes to limitation periods for personal injury cases.[187] Other legislative reforms include the adoption of the modified "Bolam principle" and provisions that allow for certain apologizes or expressions of regret to be given without equaling an admission of liability. The Commonwealth has also passed legislation to support these reforms.[188]

In the state of Victoria, the government enacted legislation in 2002 to establish a cap on general damages for injury and for loss of earnings, to change the rate used to calculate lump sum awards

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[183] *Reform 2004, supra* note 180 at A10. As part of a broader insurance crisis, tort law reforms were being introduced since early 2001 to address concerns about the availability and affordability of public liability and professional indemnity insurance.

[184] *Reform 2004, supra* note 180 at A3.

[185] The test reads: "A medical practitioner is not negligent if the treatment provided was in accordance with an opinion widely held by a significant number of respected practitioners in the field, unless the court considers that the opinion was irrational" Austl., Commonwealth, *Review of the Law of Negligence Final Report,* (2 Oct 2002), online at: <http://revofneg.treasury.gov.au/content/review2.asp> at 1; MIRP, *supra* note 178 at para. 18.

[186] MIRP, *supra* note 178 at para. 22-23.

[187] See the following reports for a description of tort law reforms by jurisdiction and the legal instruments used to implement them: *Reform 2004, supra* note 180; *Reform of Liability insurance: Progress as at 8 April 2005*, online at <http://www.treasury.gov.au> [*Reform 2005*].

[188] The Commonwealth government has some responsibilities in the insurance field and has passed statutes relating to prudential regulation, the conduct of companies and the contractual relationship between the insurer and the insured. Insurance claims can be brought in all states and the Commonwealth. To prevent plaintiffs from bringing claims in the Commonwealth jurisdiction in order to bypass state tort law reforms, the Commonwealth passed legislation containing limitation periods and caps on damages for personal injury and death consistent with those in the states. *Reform 2004, supra* note 180 at A3. *Reform 2005, ibid.*

for future economic loss and care and to protect volunteers and "good Samaritans."[189] To encourage apologies when adverse events occur, the legislation also stipulates that an apology or a payment waiver does not constitute an admission of civil liability in cases involving personal injury or death.[190] These actions also do not constitute an admission of unsatisfactory professional performance or unprofessional conduct for the purposes of professional regulation.[191] In 2003, the Government enacted further legislation to establish a threshold so that the courts cannot generally award damages for non-economic loss unless a significant injury occurred that involves either:

- whole person permanent impairment greater than 5%, assessed with reference to the American Medical Association's Guides to the Evaluation of Permanent Impairment (4th Edition);
- loss of a foetus;
- loss of a breast;
- psychological or psychiatric injury arising from the loss of a child due to an injury to the mother or foetus or child before, during or immediately after the birth of a child;
- psychiatric permanent impairment of more than 10%.[192]

In addition, the *Limitations of Actions Act* was amended to reduce the time within which claims must be made. The *Professional Standards Act 2003* allows for limited liability in certain circumstances for members of an occupational association in return for improved standards through mechanisms such as risk management strategies, but does not apply to liability for damages arising from death or personal injury.

There are no no-fault schemes in place in regards to medical malpractice in Australia. Justice Kirby of the High Court of Australia, states that Australia will be unlikely to introduce a no-fault compensation scheme for all personal injuries because:

- Accident compensation schemes privilege those who suffer injury through accident above those who are injured due to congenital damage or illness
- Since 1974 for those who enjoy a common-law right to compensation it is doubtful whether the federal parliament could abolish such a right without affording those affected "just terms" as promised by the constitutional provision limiting acquisition of property under federal law.

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[189] *Wrongs and Other Acts (Public Liability Insurance Reform) Act 2002,* (Vic.) [*WA 2002*]. This Act amends the *Wrongs Act 1958,* (Vic.) [*WA 1958*].

[190] *WA 1958*, *ibid.,* s. 14J; *WA 2002, ibid.,* s. 6. An apology is defined under the Acts as an expression of sorrow, regret or sympathy and does not include a clear acknowledgement of fault. Austl, Victorian, Department of Human Services, "Medical Indemnity Insurance," online: <www.health.vic.gov.au/a.htm>. When discussing legislative changes concerning apologizes, a Commonwealth government report stated that "Research has shown that plaintiffs — particularly medical patients — are less likely to seek recovery of damages where the medical practitioner or potential defendant has explained the cause of loss or has apologised for the loss." *Reform 2004, supra* note 180 at C7.

[191] *WA 1958, ibid. at* 14k. *WA 2002, ibid., s. 6;* The 2002 Act also makes similar amendments concerning apologies and waivers to *Coroner's Act 1985*, so they are not construed as an admission as to the cause of death. *CA 1985, supra* note 163, s. 18A. *WA 2002, ibid.,* s. 12.

[192] *WA 1958, ibid.,* ss. 28LB, 28LE, 28LF, amended by the *Wrongs and Limitation of Actions (Insurance Reform) Act 2003*and *The Wrongs and Other Acts (Laws of Negligence) Act 2003.*

He notes that it may be possible to enact no-fault legislation confined to a particular issue such as medical malpractice but this would have to run the gauntlet of constitutional provisions and human rights requirements. He also notes that in a democracy governments may be resistant to providing special legal immunity for errors that adversely affect others to one particular professional group, even in the face of strong arguments based on burden of indemnity premiums, high rates of litigation, proof of undesirable practices in medical practice and to the health care system generally.[193] He also notes that this would appear contrary to the trends in the courts in Australia, the U.S. and the U.K. and elsewhere to extend liability and reduce immunities.

Other Patient Complaint Mechanisms

In addition to a health care facility's internal complaint resolution mechanisms, patient complaints may also be addressed in the following three ways in Australia:

- through the tort system (discussed in the Compensation Systems section)
- through the disciplinary process of the health professional bodies (discussed in the Professional Regulation section); and
- through the health care complaints bodies in each state and territory and the Commonwealth Aged Care Complaints Resolution Scheme.

At the Commonwealth level, there is a national advocacy service and a complaints resolution scheme for Commonwealth funded aged care facilities. These facilities are required by the *Aged Care Act 1997* to establish an internal complaints resolution mechanism to address any complaints made by or on behalf of the care recipient.[194] Internal complaint resolution mechanisms are assessed under the Accreditation Standards and should operate in a manner that respects residents' rights contained in the Charter of Residents' Rights and Responsibilities.[195] The Charter includes the right of residents to complain and take action to resolve disputes, to be free from reprisal and to have access to advocates and other avenues of redress. Approved providers are required to advise residents of and assist them in accessing both internal and external complaints mechanisms.[196]

The Aged Care Complaints Resolution Scheme is a free external complaints mechanism established in 1997 by the Commonwealth Government to handle complaints concerning aged care services it funds.[197] The Scheme is administered by the federal Department of Health and

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[193] Kirby, *supra* note 178.
[194] *ACA, supra* note 28, ss. 56-4 (1)(a)-(b).
[195] Austl., Commonwealth, Aging and Aged Care Division, *Residential Care Manual* (Canberra: Department of Health and Aging, April 2005), s. 10.7.1 [*RCM*]. The Charter of Residents' Rights and Responsibilities are located in the *User Rights Principles 1997,* (Cth.), Schedule 1. Section 56-1 (l) of the *ACA, supra* note 28 requires approved providers to act in a manner consistent with the rights and responsibilities of residents specified in the *User Rights Principles*.
[196] *ACA, supra* note 28, s. 56-4(1)(c).
[197] *RCM, supra* note 195, s. 10.7.2.1.

Ageing and is based on alternative dispute resolution principles.[198] The legislative framework for the Scheme is contained in the *Committee Principles 1997*.[199] Anyone may make a complaint regarding potential breaches of an approved provider's responsibilities under the Act or the Aged Care Principles that "the complainant thinks is unfair or makes the affected care recipient dissatisfied with the service."[200] They can be made on an open, anonymous or confidential basis.[201] Officers conduct preliminary assessments of complaints to determine whether they should be accepted, and if accepted, whether they should be referred to another agency or resolved within the scheme using either negotiation, mediation or determination by a Complaint Resolution Committee.[202] Consisting of three independent members, a Complaints Resolution Committee is required to hold a determination hearing and act as quickly and informally as the issues allow when resolving a complaint.[203] Their decision must be made in writing, include their reasoning and be provided to both parties.[204] Providers are required by the *Aged Care Act 1997* to comply with a Committee's determinations.[205] To ensure facilities have complied with any course of action set out in the Committee's decision, the Compliance Section of the Department of Health and Ageing monitors the facility's implementation progress approximately 6 weeks after the decision, unless a longer implementation timeframe is given.[206] Parties can also apply to have Committee decisions reviewed by a Determination Review Panel.[207]

In 2000, the Office of Commissioner of Complaints was established by the Commonwealth government. The Commissioner's functions include receiving complaints about the Scheme's operation, overseeing its effectiveness and managing the determination process.[208] Complaint Resolution Committees must refer systemic or serious isolated issues to the Commissioner, who in turn must ensure these issues are referred to the Aged Care Standards and Accreditation Agency.[209]

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[198] Austl., Commonwealth, Office of the Commissioner for Complaints, *Annual Report (1 July 2003 – 30 June 2004)*, (Canberra: Commissioner for Complaints, 2004) at 8 [OCC 2004].

[199] *CP 1997, supra* note 200, c. 3, part 2, made under s. 96-1(1) *ACA, supra* note 28.

[200] *Committee Principles 1997,* (Cth.), s. 10.38 [*CP 1997*].

[201] *Ibid., s.* 10.39.

[202] *Ibid.,* s. 10.42. Assessments must be completed within 14 days of receiving the complaint under the legislation and often include site visits as a matter of policy. Section 10.45 of the Principles lays out grounds for refusal of complaints, such as when they are frivolous or vexatious or already subject to a legal proceeding. Previously, a complaint had to go through all elements of the process (such as negotiation, mediation, and determination). Legislative changes in 2004 gave the Scheme the capacity to decide at the preliminary stage which method is best suited to resolving the complaint. OCC 2004, *supra* note 198 at iii, 10, 11.

[203] *CP 1997, ibid.,* s. 10.65, 10.81. Committee members cannot be federal officers or employees and are chosen from a panel appointed by the Secretary of the Department (Section 10.79).Committees are not bound by rules of evidence and may receive submissions orally or in writing. Parties are not entitled to legal representation at determination hearings (Section 10.66 (1)).

[204] *CP 1997, ibid., s.* 10.68.

[205] *ACA, supra* note 28, s. 56-4(1)(e). It should be noted that Committees must not make decisions that would require providers to go beyond their responsibilities under the Act and Aged Care Principles (*CP 1997, supra* note 200, s. 10.35 (i)). Committee determinations are actions that can be required of the provider, while recommendations are non binding actions that the Committee feels should be taken in order to resolve the complaint. Austl., Commonwealth, Office of the Commissioner for Complaints, "Fact Sheet: Attending a Hearing" at 3, online: <http://www.cfc.health.gov.au/doccrs/pdf/crs_attendingahearing.pdf> [Fact Sheet].

[206] Fact Sheet, i*bid.* at 2.

[207] *CP 1997, supra* note 200, s. 10.73.

[208] *CP 1997, supra* note 200, ss. 10.34A, 10.35A.

[209] *CP 1997, supra* note 200, ss. 10.35 (h), 10.35A(e).

Evidence provided to the Senate Inquiry into aged care suggested a number of deficiencies in the operation of the Scheme and included concerns about its accessibility, responsiveness, and complexity. Submissions noted that a number of complaints are not accepted because staff reports and documentation are not available to substantiate breaches of the standards. The Senate Committee noted that the Scheme had a relatively high rate of non acceptance and held that the strictness of the Scheme's criteria for accepting complaints discourages many potential complainants.[210] The Committee also held that whistleblowing legislation is required to protect people, especially staff, who disclose inadequate standards of care.[211]

The Australian Health Care Agreements require all states to have in place independent complaints bodies to resolve complaints about the provision of public hospital services and Public Hospital Patient Charters.[212] At a minimum, the complaints body must be independent of the State Health Department and public hospital service providers.[213] It must also have the power to investigate, conciliate and/or adjudicate complaints, as well as to recommend systemic and specific improvements to public hospital service delivery.

The Public Hospitals Patient Charters set out the rights and responsibilities of public hospitals and consumers when receiving a service in a public hospital.[214] Under the current agreement, the Charter must outline the process for lodging complaints and state that complaints can be referred to an independent complaints body.[215] In 2004, the Commonwealth Minister for Health and Aging released the Private Patients' Hospital Charter, a statement issued under section 73F of the *National Health Act 1953*.[216] The Charter acts as a guide to what private patients can reasonably require from hospitals, practitioners and insurance funds. It states that private patients are entitled to complain about the service they receive in hospital and directs them to first approach the staff, then the hospital and lastly, the independent complaints bodies in each state.[217]

The set-up, role and functions of the independent complaints bodies differ from state to state. In Victoria, the Health Services Commissioner is established by the *Health Services (Conciliation and Review) Act 1987.* The purposes of the Act are to set up the Health Services Commissioner, to provide an independent and accessible review mechanism for health service users, and to

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[210] *Senate Report,* supra note 38, ss. 3.141-3.144. In 2003-2004, 13% of all complainants made to the Scheme were not accepted.
[211] *Senate Report, supra* note 38, s. 3.153.
[212] *Agreement, supra* note 53, Schedule D.
[213] *Agreement, supra* note 53, s. 5, Schedule D.
[214] *Agreement, supra* note 53, s. 3(b)(iv), Schedule D. It is does not appear that these Charters have legal effect (a search of the AustLII database showed no cases where the Charter had been used in court proceedings).
[215] *Agreement, supra* note 53, ss. 3 (b)(ii), 3 (b)(iii), 5, Schedule D.
[216] Austl., Commonwealth, Department of Health and Aging, "Private Health Insurance – Private Patients' Hospital Charter", online: <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-privatehealth-consumers-charter-index.htm>.
[217] Austl., Commonwealth, Department of Health and Aging, *Private Patients' Hospital Charter*, (Canberra: Commonwealth Copyright Administration, 2004) online: <http://www.health.gov.au/internet/wcms/publishing.nsf/Content/health-privatehealth-consumers-charter-index.htm/$FILE/ppbooklet.pdf> at 21-22.

provide a means of reviewing and improving the quality of health services.[218] It is a complaint *resolution* service through conciliation. Complaints concerning the unreasonable behaviour of health service providers and access to and management of health information under the *Health Records Act 2001* can be made to the Commissioner.[219] Complaints can be made by a patient, their chosen representative, or if they are unable to choose a representative, an individual deemed to have sufficient interest in the complaint or a provider.[220]

When a complaint is made, it is recorded in a database and an assessment officer assesses whether it is in the Commissioner's jurisdiction and how it may be resolved.[221] The majority of cases are resolved informally at the assessment stage, which has a statutory limit of 84 days.[222] At this point, assessment officers will recommend unresolved cases be closed, transferred to an external agency or resolved internally through conciliation or investigation. The Commissioner must reject complaints which have already been determined by a Coroner or court, administrative or industrial tribunal, or registration board.[223] Complaints cannot be investigated or forwarded to conciliation unless the Commissioner is satisfied that the patient or his/her representative has taken all reasonable steps to resolve the complaint with the provider. Complaints involving registered providers are referred to the appropriate professional body, if, after consultation with the body, the Commissioner considers they have the power to resolve the issue and it is not appropriate for conciliation.

Accepted complaints deemed suitable for conciliation must be referred without delay.[224] Conciliation is a voluntary process that aims to resolve complaints through informal, privileged discussions between the parties facilitated by the conciliator.[225] Anything said or admitted during conciliation is inadmissible in a court or tribunal.[226] Conciliation may involve claims for damages or compensation and if settled, legal release documents are prepared.[227] If the parties agree, an independent expert opinion may be arranged by the conciliator in disputes over liability. Should systemic issues concerning the health system arise during conciliation, the conciliator is more proactive in working with the parties to effectively address these issues on a systems level as part of the settlement.[228] If a matter is unable to be conciliated or if further investigation of an unsuccessfully conciliated matter is supported by the conciliator, the

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[218] *HSCRA, supra* note 156, s. 1.
[219] *HSCRA*, *supra* note 156, s. 16 (1). Austl., Victoria, Health Services Commissioner, *2004 Annual Report* (Melbourne, 2004), online: <http://www.health.vic.gov.au/hsc/annrep0304.pdf> at 10 [HSC 2004]. The definition of a provider in the Act includes both public and private hospitals, their CEOs, the Secretary to the Department of Human Services, local government bodies that provide health services and any person or body who holds themselves out as providing a health service. *HSCRA, supra* note 156, s. 3.
[220] *HSCRA, supra* note 156, s. 15. Complaints may be made orally or in writing, but oral complaints must be confirmed in writing at a latter date, unless the Commissioner is satisfied there is a good reason not to do so. A complainant must provide his or her name, although the Commissioner has discretion to keep this information confidential under special circumstances. *HSCRA, supra* note 156, s. 17. Complaints not confirmed in writing are closed unless they are identified as serious. HSC 2004, *supra* note 219 at 16.
[221] HSC 2004, *supra* note 219 at 16-18.
[222] *HSCRA, supra* note 156, ss. 8, 9(AA), 9(A).
[223] *HSCRA, supra* note 156, s. 19(2).
[224] *HSCRA, supra* note 156, s. 19 (10).
[225] HSC 2004, *supra* note 219 at 17; *HSCRA, supra* note 156, ss. 20 (5), 20 (15).
[226] *HSCRA, supra* note 156, s. 20 (14).
[227] HSC 2004, *supra* note 219 at 17.
[228] HSC 2004, *supra* note 219 at 20. See this page for an example of such a situation.

Commissioner may investigate the matter and if upheld, determine remedies.[229] Investigations are rare. Of the 2587 closed cases the Health Services Commissioner dealt with in 2003-2004, 1100 were closed in assessment, 393 in Conciliation and 5 in Investigation.[230]

In 2003, the New South Wales Health Commission, on behalf of the Australasian Council of Health Care Complaints Commissioners, collaborated on a project to improve the way complaints are managed by health care services and linked to safety and quality improvement.[231] Drawing upon existing policies, law and standards as well as other sources, the project developed guidelines, entitled *Better Practice Guidelines on Complaints Management for Health Care Services*, and a complaints management handbook.[232] The project recommended that the Australasian Council of Health Care Complaints Commissioners and state and territory departments create a forum for sharing complaints information to facilitate improvements to health care services.[233] The current Australian Health Care agreements contain a provision whereby states agree to adopt any future nationally consistent approach to collecting and reporting health complaints data in order to improve the quality of public hospital services for patients.[234]

The Private Health Insurance Ombudsman is a statutory body funded by the Commonwealth through a levy on private insurance funds and set up by an amendment to the *National Health Act 1953*.[235] The Ombudsman only addresses complaints about the health insurance component of the provision of health services. Thus a person may make a complaint about an individual health professional, a private hospital or the insurance company but only in respect to health insurance entitlements. Complaints about the quality and safety of care are directed to complaints bodies at the state rather than federal level.

Adverse Event Reporting Systems

At the national level, adverse event reporting systems for drugs and medical devices are maintained by the Therapeutic Goods Administration.[236]

There is also an Australian Incident Monitoring System (AIMS) initiated by a NGO, the Australian Patient Safety Foundation (ASPF). It is a national level voluntary system, in which

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[229] *HSCRA, supra* note 156 ss. 20(9), 21(1).
[230] HSC 2004, *supra* note 219 at 17.
[231] Austl., New South Wales, Health Care Complaints Commission, *HCCC Annual Report 2003-2004*, online: <http://www.hccc.nsw.gov.au/hccc/pubs/ar_03_04.pdf> [HCCC 2004]. The project, entitled *Turning wrongs into rights: learning from consumer reported incidents*, was funded by the Australian Council for Safety and Quality in Health Care and other collaborators included Royal Australasian College of Physicians and the Health Issues Centre.
[232] Austl., Commonwealth, Australian Council on Safety and Quality in Health Care, *Better Practice Guidelines on Complaints Management for Health Care Services* (Canberra: Office of the Safety and Quality Council, 2004), online: <http://www.safetyandquality.org/guidecomplnts.pdf>.
[233] HCCC 2004, *supra* note 231 at 38.
[234] *Agreement, supra* note 53, s. 7, Schedule D.
[235] Austl., Commonwealth, Private Health Insurance Ombudsman, online : <http://www.phio.org.au/home.php>.
[236] See the Product regulation section for more details on these systems.

the ASPF collects anonymous data about clinical incidents in health units that use its software and then aggregates it to provide comparative performance data for health units and help identify system-based prevention strategies.[237] The federal Minister of Health and Ageing has declared participation in AIMS to be a quality activity under Part VC of the *Health Insurance Act 1973* and therefore health professionals who use the system receive the protections of the Commonwealth Qualified Privilege Scheme.[238] Its software was recently implemented in all public hospitals in New South Wales and is now used by 54 percent of the Australian public health system.[239]

In the State of Victoria, it is a Department of Human Services funding requirement that public health services have a reporting system for clinical incidents, including adverse events and near misses.[240] However, the Department does not specify the form of the system or how it should operate. The Auditor General noted that this situation has created a barrier to statewide data collection, as there are different systems at the hospital level collecting different information.[241] The report recommended that incident reporting systems should meet the Australian Council for Safety and Quality in Health Care minimum guidelines and that the Department should develop recommended minimum data sets for these systems.[242]

Victoria also has a statewide sentinel events reporting requirement that covers "relatively infrequent, clear-cut events that occur independently of a patient's condition, may be linked to hospital systems and process deficiencies and may result in adverse outcomes for patients."[243] All public health services are required to report sentinel events within three days and within sixty days, they must submit a root cause analysis (RCA) and a risk reduction action plan (RRAP) to the Department.[244] These requirements are part of the Department's Clinical Risk Management Strategy. The Department sends sentinel events reports to expert bodies for assessment and recommendations from these bodies are forwarded to the health service.[245] A monthly newsletter, *Risk Watch*, contains de-identified case summaries of reported sentinel events and recommendations concerning system issues and is publicly available on the Department's

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[237] Australian Patient Safety Foundation Inc., "About Us", online: < http://www.apsf.net.au/about.php>.

[238] Patient Safety International, "Qualified Privilege & AIMS" online: <http://www.patientsafetyint.com/qualified.aspx>. For more details about the Commonwealth Scheme and its protections, see the Rules of Evidence section.

[239] Patient Safety International, Press Release, "NSW Public Health System Installs Patient Safety Software" (23 Feb 2005) online: <http://www.patientsafetyint.com/press.aspx?ID=17>.

[240] Austl., Victoria, Auditor General Victoria, *Managing Patient Safety in Public Hospitals* (Melbourne: Government Printer for the State of Victoria, 2005) at 33 [*Managing Safety*]. Austl, Victoria, Department of Human Services, *Victoria –Public Hospitals and mental health services: Policy and funding guidelines 2005-2006* (Melbourne: Big Print, 2005) at 39 [*PFG 05-06*].

[241] *PFG 05-06, ibid.* at 78.

[242] *PFG 05-06, ibid.* at 38.

[243] Austl., Victoria, Department of Human Services, "Sentinel Event Reporting Form 2005-2006," online: <http://www.health.vic.gov.au/clinrisk/sentin.htm>. This form lists nine reportable sentinel events. This requirement stems from the Department's policy and funding guidelines. *PFG 05-06, ibid.* at 39.

[244] *PFG 05-06, ibid.* at 39.

[245] Austl., Victoria, Department of Human Services, *Sentinel Event program: Annual report 2003-04*, (Burwood: BPA Print Group, 2004), online: <http://www.health.vic.gov.au/clinrisk/sentin.htm#anrep0304> at 4 [*Sentinel AR 03-04*].

website.[246] The Department also produces a public sentinel events annual report.[247] The Auditor General's report noted that of the 85 sentinel events reported to DHS in 2003-04, only 35 percent were followed by timely RCAs, and some RCAs and RRAPs were up to 255 days late.[248]

The Victorian government has also established a number of consultative councils under the *Health Act 1958*, which analyze mortality and morbidity data in the areas of surgery, anaesthesia, obstetrics and paediatrics. The Victorian Surgical Consultative Council (VSCC) and the Victorian Consultative Council on Anaesthetic Mortality and Morbidity (VCCAMM) maintain voluntary reporting systems that collect information on adverse events.[249] Reports are de-identified before being discussed by these councils and strategies to improve practice are then disseminated using a variety of mechanisms. Under section 24A of the *Health Act 1958*, members of these two councils cannot be compelled to disclose information or produce documents in any proceeding and cannot disclose information related to the councils' work unless they have approval of the reporter and the Minister. However, de-identified information can be used in documents. The VCCAMM has expressed some concern about the reliability of its voluntary reporting system, as its reporting rates are lower than some other states.[250]

The Consultative Council on Obstetric and Paediatric Mortality and Morbidity (CCOPMM) analyses maternal, perinatal and paediatric deaths and assesses their preventability.[251] All births, including still births, must be reported to the Council by either the hospital, medical practitioners, or midwives involved.[252] Victoria's Registrar of Births, Deaths and Marriages is required by law to notify the Council of any still-births or child deaths it knows of and forward the appropriate documentation.[253] Under the *Health Act 1958*, the Council may request further information from a health service provider and that provider is authorized to share it despite any other law to the contrary.[254] Information provided to the Council is confidential and cannot be compelled in any proceeding, except for already published information.[255] The Council can decide to divulge information to specified groups, such the medical practitioners board, if it determines it is in the public interest to do so.[256]

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[246] Austl, Victoria, Department of Human Services, "Risk watch Newsletter," online: <http://www.health.vic.gov.au/clinrisk/index.htm>.
[247] *Sentinel AR 03-04, supra* note 245 at 4.
[248] It also cited the DHS Clinical risk management Reference group, who noted that hospital compliance with the reporting requirements and Departmental recommendations varied. *Managing Safety, supra* note 240 at 76.
[249] VCCAMM, online: < http://www.health.vic.gov.au/vccamm/>.
[250] Victoria's 1994-1996 rate was 53 deaths per million, compared to 238 deaths per million in Western Australia, where reporting is mandatory. VCCAMM, "Operation of the Council", online: <http://www.health.vic.gov.au/vccamm/>.
[251] CCOPMM, "Overview", online: < http://www.health.vic.gov.au/perinatal/ccopmm/>.
[252] *HA, supra* note 100, s. 162G.
[253] *Births, Deaths and Marriages Registration Act 1996*, (Vic.), s. 49B .
[254] *HA, supra* note 100, s. 162FA.
[255] *HA, supra* note 100, s. 162H.
[256] *HA, supra* note 100, s. 162FB. The CCOPMM has indicated it would only do so after "very careful consideration of the issues, including the need to encourage full and frank disclosures by Health providers." "Information gathering and disclosure", CCOPMM, online: < http://www.health.vic.gov.au/perinatal/ccopmm/>.

Other Legislative Instruments

Qualified Privilege legislation

The Commonwealth, all state governments, and ACT have enacted "qualified privilege" legislation to protect information used in quality assurance or practice improvement programs. At the Commonwealth level, the *Health Insurance (Quality Assurance Confidentiality) Amendment Act 1992* (Commonwealth) amended *Health Insurance Act 1973*. The object of the amending Act is to encourage efficient quality assurance activities in connection with the provision of certain health services.

The Commonwealth scheme for quality assurance protections is intended to complement state schemes and thus only applies to quality assurance processes that:

- take place in more than one state; or
- where the state has no quality assurance protections; or
- involve a methodology which is new in Australia; or
- has the potential to affect the quality of care on a national scale.

An application for a quality assurance activity (i.e. activity, person or circumstances) to be granted the Commonwealth privilege must be made to the federal Minister for Health and Ageing. The Minister must be satisfied that the person is authorized to undertake the activity and it is in the public interest to protect the activity. Public interest criteria the Minister must consider are laid out in the *Health Insurance Regulations 1975* and include whether protecting the activity will make it effective by:

- encouraging full or greater participation in the activity; and
- encouraging acceptance, implementation or monitoring of recommendations arising from the activity.[257]

The Minister may disclose information about serious crimes to the appropriate authorities.[258]

Only designated information that identifies individuals and became known or was generated solely as part of the quality assurance process is kept confidential. Aggregate non-identifying information is not covered by the privilege. The privilege also grants protection from civil proceedings, except in relation to procedural fairness, for a member of a committee undertaking declared quality assurance activities who acts in good faith.[259]

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[257] Austl, Commonwealth, Department of Health and Aging, "Commonwealth Qualified Privilege Scheme", online: <http://www7.health.gov.au/pq/sq/qainfo.htm>.
[258] *Health Insurance Act 1973,* (Cth.), s. 124Z [*HIA*].
[259] *Ibid.,* s. 124ZB.

The following state and territory acts contain quality assurance privileges: *Health Act 1993* (ACT) s. 8-16, *Health Administration Act 1982* (NSW) s20D-20K, *Health Services Act 1991* (Qld) s 30-38, *South Australian Health Commission Act 1976* s 64D, *Health Act 1997* (Tas.) s 4, *Health Services Act 1988* (Vic) s139, *Health Services Quality Improvement Act 1994* (WA). The content of the qualified privilege acts varies from state to state.[260]

In Victoria, section 139 of the *Health Services Act 1988* allows "quality assurance bodies of registered funded agencies, health service establishments, psychiatric services or professional associations to obtain statutory immunity to promote full and open discussions of quality issues."[261] Confidential information generated by approved quality assurance bodies is not admissible in court proceedings and cannot be disclosed to persons outside Quality Assurance Committees. Under sub-section 139(1) of the Act, the Minister for Health can declare a specified committee, council or other body as 'an approved quality assurance body' if he or she is satisfied that:

- the body is established under the by-laws or constitution of the agency;
- its functions include the assessment and evaluation of the quality of health services provided by the agency, including the review of clinical practices or clinical competence of persons providing those services;
- the carrying out of its functions and powers would be facilitated by the provision of certain immunities in respect of proceedings; and
- it is in the public interest that persons be prohibited from disclosing information given to it in the course of the carrying out of its functions.[262]

The Minister's formal declaration is published in the Gazette.

There exist concerns over the completeness of qualified privilege protection, as it is unclear how the legislation interacts with other types of public interest legislation. State and Commonwealth Freedom of Information Acts may potentially prevail over qualified privilege laws in particular circumstances.[263] For example, it appears that the *Commonwealth Freedom of Information Act* may permit the release of documents under the Commonwealth scheme, as the *Health Insurance Act* is not listed as an exempt Act.[264] A tribunal in the appropriate circumstances could decide that public interest considerations under the Freedom of Information laws override those associated with qualified privilege laws.[265] State administrative tribunals who have attempted to balance these competing public interests have generally held that the public interest is best

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[260] Refer to description of the legislation from each state in: Austl., Commonwealth, Australian Council for Safety and Quality in Health Care, *National Report on Qualified Privilege* (2002), online: <http://www.safetyandquality.org/qual_priv1.pdf> [*Qualified Privilege*].
[261] Austl., Victoria, Department of Human Services, "Statutory Immunity: Information for Public Hospitals and Health Services", online: Department of Human Services <http://www.health.vic.gov.au/statim/index.htm>.
[262] *Ibid.*
[263] Austl., Commonwealth, Australian Council for Safety and Quality in Health Care, *Improving the Consistency of Approaches to Qualified Privilege Schemes* (Canberra: Commonwealth Copyright Administration, 2003), online: <http://www.safetyandquality.org/QualifiedPrivilege_web.pdf> at 41 [*Improving Consistency*].
[264] Austl., Commonwealth, Safety and Quality Council, *The Public Interest in Health Care Qualified Privilege*, (August 2001) at 14 [*Public Interest*].
[265] *Qualified Privilege, supra* note 260 at 11.

served by keeping quality assurance activities confidential, but there have been cases where tribunals have emphasized the need for openness and transparency in the health care system and the release of certain quality assurance information has been ordered.[266] Even when qualified privilege legislation states that it prevails to the extent of an inconsistency with other laws or acts, the Freedom of Information laws may still be applicable.[267] A 2003 report by the Australian Safety and Quality Council recommended that each jurisdiction analyze how their qualified privilege legislation interacts with other relevant acts and clarify the relationship in order to ensure that the health care community and the general public have confidence in the integrity of the qualified privilege system.[268] The report also contained ten proposed national qualified privilege guidelines and six principles important for the efficient and effective administration of qualified privilege legislation, which included:

- The public interest should be thoroughly evaluated by jurisdictions before granting an activity protection and Ministerial declarations should be reviewed regularly (Guideline 2 & 9);
- Jurisdictions should regularly report to the public regarding the number of activities protected, how they are monitored and the purpose of the privilege. In all jurisdictions (except Tasmania), declared committees and activities should be required to periodically report non-individually-identifying information to the Minister and the public using a range of parameters (Guideline 10);
- The extent of legislative protection should be clear for new and continuing members of declared activities in order to manage expectations (Guideline 8);
- Qualified privilege protection should be available only:
    - to the extent needed to ensure that quality assurance activities are not impeded by health practitioners' reasonable fear of unreasonable adverse professional consequences of disclosure; and
    - if there is no paramount countervailing public interest that necessitates the disclosure of protected information (Principal 1).[269]

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[266] *Qualified Privilege, supra* note 260 at 12 Australian Council for Safety and Quality; *Improving Consistency, supra* note 263 at 41.
[267] *Improving Consistency, supra* note 263 at 41.
[268] *Improving Consistency, supra* note 263 at 10, 17. At 17, the report cites the "The Age Newspaper case" as one example where healthcare practitioners may withdraw or reduce their participation in quality assurance activities when they discover that protections are not as complete as they thought. Journalists from the Age newspaper made an application for safety and quality program documents from a variety of hospitals under the Victorian Freedom of Information Act. Arguments concerning the release of the documents focused on FOI exemption clauses rather than Victoria's qualified privilege legislation, as the former potentially gave protection to more documents. In balancing the public interests, the Deputy President of the tribunal held that information that identified individuals should be protected as clinician resistance and apprehension would hurt future information gathering, but non-individually identifying material could be released. It was reported anecdotally that clinician participation in quality assurance activities substantially decreased at the Alfred Hospital, one of the hospitals concerned in the case. *Public Interest, supra* note 264 at 7-8.
[269] *Improving Consistency, supra* note 263 at 3-4, 17-19.