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Patient Safety Law:
From Silos to Systems

Appendix 1:
KEY CONCEPTS

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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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Patient Safety and Governance

What is the most appropriate way to undertake the governance of patient safety in health systems is one of the policy questions of our times. In this appendix we define and discuss the concepts of patient safety and governance and the linkages between them and establish an analytical framework to assess the governance structures around patient safety that use law as a framework.

Delineating Patient Safety and Healthcare Quality

The quality of healthcare is a longstanding policy issue but it was not until the end of last century that the policy discussions around healthcare quality were overtaken by discussions of patient safety or the lack of it. At that point patient safety began to be addressed as a separate issue from healthcare quality – though some critics remain concerned about whether the separation of these issues accords any greater priority to one over the other and therefore greater improvements in safety or quality.[1] The health system was not alone in addressing these issues. Other sectors too are also addressing issues relating to safety and quality and there is also some debate whether making safety a distinct issue from quality is successful in respect of ensuring safety or quality.

Debates about the utility of separating the concept of healthcare quality and patient safety aside, this project does separate safety from quality as does current practice, policy and some new legislative initiatives. The focus of this project is therefore patient safety, so as a starting point it is as well to delineate the concept of patient safety from the concept of healthcare quality as each concept, either in meaning or application, overlaps with the other.

There are differing definitions or interpretations of 'patient safety'. Broadly, 'safety' is defined in dictionaries to mean that a person is not in danger or likely to be harmed.[2] Safety, in the context of section 264(2)(b) of the *Canadian Criminal Code*, has been defined by the courts as "freedom from physical harm and apprehension of mental, emotional and psychological trauma."[3] These definitions recognize that harm is not purely a physical experience and is experienced at a number of levels including emotional, psychological and, perhaps also, spiritual. An obvious example of harm as expressed more broadly would be where blood transfusions are administered to a person of the Jehovah's Witness faith – no physical harm may be experienced, indeed the

[1] See for example, Janet Storch, "Patient Safety: Is it Just Another Bandwagon?" (2005) 18:2 Can J. Nurs. Leadersh. 39.

[2] *Cambridge Advanced Learners Dictionary* online: Cambridge Dictionary <http://dictionary.cambridge.org/> The Oxford English Dictionary states safety is "the state of being safe; exemption from hurt or injury; freedom from danger" and "the quality of being unlikely to cause or occasion hurt or injury; freedom from dangerousness; safeness. *with safety*, without occasioning danger or risk." Oxford English Dictionary, online: OED <http://dictionary.oed.com/>.

[3] *R v. Theysen* (1997) 44 Alta. L.R. 3d 364 (Prov. Ct.).

opposite, but the emotional and spiritual trauma may be devastating.[4] As much as avoidance of harmful outcomes is part of any definition of 'patient safety' and, more broadly, must be part of any discussion of what to do about patient safety, we believe that 'harm' should be more broadly defined to include mental, emotional, psychological and spiritual trauma – as distinguished from being unhappy or upset which is more in the realm of quality.

We note that much of the empirical studies of the incidence of unsafe care focus on assessing physical harms experienced by patients. There are a number of reasons why empirical research into patient safety focuses to a large extent on physical harms. First, physical harm is significantly easier to identify and is considered more objective, whereas emotional or spiritual harm is a more subjective experience. Non-physical harms are likely to be more difficult to identify in retrospective chart analyses. In short, physical harms are easier to study. Second, organized medicine also has a bio-medical orientation that focuses on physical harms and which has historically marginalized concerns about psychological, emotional, spiritual or even social harms.[5] However, emotional, psychological, and spiritual harms can be just as, if not more so in some circumstances, destructive to the patient, his or her family, and the community, as physical harms.

In-as-much as legal considerations shape the discussion of safety, the law focuses primarily on physical harm, as a prerequisite for criminal offences and for civil actions seeking compensation. Some concerns about patient safety are placed into sharper relief in the public consciousness, and certainly in the consciousness of health care providers, as a consequence of legal mechanisms such as coroner's inquests, public inquiries, criminal proceedings and civil proceedings. This in turn may shape policy-making so that it focuses on physical harm. Some suggest that the legal system, focusing as it does on harm, dwells too much on the outcome of error for the individual and does not sufficiently focus on the processes through which errors occur and, consequently, on learning from error (see further discussion below). A definitional requirement that an action must result in harm also has two other consequences. First, it turns considerations of patient safety into retrospective analyses of unsafe acts, rather than a prospective examination of systems and people. Retrospective analyses of events that resulted in harm may also foster a need to place of blame on individuals through legal processes and discourage learning from error. Second, focusing on harmful outcomes may mean that those events where no discernable harm results or where near misses occur are overlooked. However, it is also important to note that a focus on harms experienced by patients may limit or focus on blame. So, although harm is not an unimportant concept, it does not find a prominent place in our definition of "patient safety".

The second approach, and the approach we prefer, is to focus primarily on the types of actions or omissions that may, if unchecked, result in harm. The Canadian Patient Safety Dictionary defines patient safety as "the reduction and mitigation of unsafe acts within the health-care system, as well as through the use of best practices shown to lead to

[4] *Malette v Shulman* (1987), 72 O.R. (2d) 417 (C.A.). It also may be an issue for persons from other cultures.

[5] See for example, Norman Daniels, *Just Health Care* (Cambridge: Cambridge University Press, 1985).

optimal patient outcomes."[6] The latter part of this definition is intended to be more expansive and positive, but moves towards the domain of quality illustrating the overlaps that can arise between quality and safety. Therefore, to distinguish as clearly as possible between safety and quality we focus on the first part of the definition. The Dictionary defines 'unsafe acts' as "error, violation and sabotage". It explains:

> Error should be defined as the failure to complete a planned action as it was intended, or when an incorrect plan is used in an attempt to achieve a given aim. Violation should be defined as representing a deliberate deviation from standards, rules or safe operating procedures. Sabotage should be defined as an activity in which both the acts and the harm or damage are intended.[7]

The Institute of Medicine (IOM) defines 'patient safety' as "freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximizes the likelihood of intercepting them when they occur."[8] The IOM's focus on the mechanism through which harms occur, i.e. 'accidental' injury, excludes harm that arises from deliberate malicious acts by actors in the health care system. Malicious acts increase danger and likelihood of harm to patients and are a real safety issue in the health care system. A typology of this type is vulnerable to criticism that it creates room for a blame culture which is anathema to a systems approach to safety (discussed below). Given our focus on governance choices that involve the use of legal instruments to improve patient safety, a focus on types of unsafe care, as opposed to results, allows one mechanism of analyzing the intentions and effects of legal instruments.

Quality is a broader concept. To achieve quality one achieves a degree of excellence that encompasses measures to ensure patient safety, practice that is consistent with socially defined values and norms, practice that is consistent with current medical knowledge, and customization (the ability to meet customer specific values and expectations).

In respect of 'quality' the Institute of Medicine suggests that there are three domains of quality: safe care; practice that is consistent with current medical knowledge; and customization.[9] We suggest that this formulation does not fully capture 'quality'. The elusive domain missing from the IOM's formulation is touched upon by Donabedian who suggests that quality also includes conformity to "socially defined values and norms that govern the interaction of individuals in general and in particular situations."[10] Socially defined values and norms may differ from customer specific values and experiences. Customer specific values imply a notion of an understanding of medicine and health care that has its roots in the market. Relationships with others who are in that market are

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[6] J. Davies, P. Hebert, C. Hoffman & the Royal College of Physicians and Surgeons of Canada, *Canadian Patient Safety Dictionary* (Ottawa: College of Physicians and Surgeons of Canada, 2003) at 12. [Canadian Patient Safety Dictionary.]
[7] *Ibid* at 57.
[8] Institute of Medicine, *To Err is Human: Building a Safer Health System*, (Washington, D.C.: National Academy Press, 2000).
[9] *Ibid* at 18.
[10] *Ibid*.

almost purely instrumental, relating to the purchase or use of products and focus on contractual obligations.[11] Socially defined values and norms include more expansive social, moral, ethical, and legal concerns, for example, such legal and ethical requirements as informed consent.

So, in practice, what are the distinctions between healthcare quality and patient safety? An 'unsafe' act may result from an isolated error and be a patient safety issue but it may not indicate an overall lack of healthcare 'quality'. The best technical treatment may be 'safe' in the sense that it does not cause physical harm or emotional, psychological, or spiritual trauma but it may not be 'quality' care if it is delivered in a manner that overrides autonomy or is exploitative or humiliating. So called 'defensive medicine' may not physically or emotionally 'harm' the patient and therefore is 'safe', but it is not 'quality' care as it wastes societal resources to say nothing of putting the patient through unnecessary diagnosis or treatment.

As these distinctions illustrate, healthcare quality and patient safety overlap in places but are fundamentally different concepts with a substantially different focus: one takes a holistic view of what good care is; the other focuses on the avoidance of serious harm. However, the differences go further than this when one considers public perceptions. It may be fairly said that, to the general public, quality is important, but safety is paramount. A number of commentators have explored what they consider to be contemporary preoccupation with risk.[12] All note that the concerns of risk societies are defensive, focusing on risk avoidance and protection from harm.[13] Patient safety focuses on the risk that a particular course of action may cause harm and how to manage the risk by developing strategies to prevent harm. Healthcare quality is seen to focus on how good services are and while safe care is certainly a component of this it is not the focus. Quality assurance processes and safety assurance processes are also very different in process and desired outcome.

The Patient Safety Problem

Now that we have defined some key concepts, we need to set out the problem and the problem is that the provision of health care, in Canada and in other countries around the world, is not as safe as it could be. A number of preventable episodes of unsafe care occur in every health care setting every day.

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[11] Ruth Malone, "Policy as Product" (1999) 29:3 Hastings Centre Report 16.

[12] The most prominent are U. Beck, *Risk Society – Towards a New Modernity* (London: Sage, 1992) and A. Giddens *Modernity and Self-Identity* (Cambridge: Polity Press in Association with Blackwell Publishers Oxford, 1991).

[13] H. Kemshall, "Conflicting Knowledge on Risk: The Case of Risk Knowledge in the Probation Service" (2000) 2:2 Health, Risk & Society 143 at 144.

The Problem

The problem is that the care and treatment that Canadians receive within all sectors of the health care system in Canada is not always safe. Canadians have a number of reasons to suspect that this is so – the publicity that some unsafe acts have garnered and anecdotal and empirical evidence that care and treatment received in hospitals and when receiving health care more generally can be unsafe. It has also become apparent that the costs of unsafe health services – personal and fiscal – to individuals, their families and their communities and to the state as a whole are high. Recent surveys indicate that indeed many Canadians have concerns about the quality of the health services that they are receiving. For example, the Commonwealth Fund 2002 International Health Policy Survey finds that one in four Canadians with health problems believes that the quality of health care in their country has deteriorated in the past two years.[14]

The Publicity

Over the past fifteen years there has been greater publicity about allegations of unsafe treatment and care within Canada and in other countries. In Canada, unsafe care has been highlighted in a number of fora in relation to a number of different aspects of the health care system. Some of these are listed below:

- In relation to public health, a Royal Commission of Inquiry investigated the management and operation of the blood system in Canada (1998),[15] and an Independent Commission was established by the Government of Ontario under public health legislation to investigate how the SARS virus came to Ontario, how the virus spread and was dealt with (2004).[16]
- In relation to hospital care, a 1998 Coroner's Inquest investigated the deaths of 12 children who underwent pediatric cardiac surgery in Manitoba.[17]
- In relation to long-term care facilities, in 2004 there was extensive media coverage of allegations of abuse at long-term care facilities in Québec and Ontario. In Québec the Minister placed the institution at the centre of the allegations under trusteeship and conducted audits of all other facilities in the

[14] The Commonwealth Fund, *The Canadian Health Care System: Views and Experiences of Adults with Health Problems. Findings from the Commonwealth Fund 2002 International Health Policy Survey* Pub no 641 (May 2003).

[15] Commission of Inquiry on the Blood System in Canada, *Final Report: Commission of Inquiry on the Blood System in Canada*, by Horace Krever (Ottawa: Public Works and Government Services Canada, 1997).

[16] Canada, Government of Ontario, *The Sars Commission*, online: Sars Commission <http://www.sarscommission.ca/>.

[17] Winnipeg Provincial Court, *The Report of the Manitoba Pediatric Cardiac Surgery Inquest: An Inquiry Into Twelve Deaths at the Winnipeg Health Sciences Centre in 1994*, by Associate Chief Judge Murray Sinclair (Winnipeg: Provincial Court of Manitoba, 1998) online at: Pediatric Cardiac Inquest <http://www.paediatriccardicinquest.mb.ca>.

province. The Ordre des infirmières et infirmiers du Québec also instituted an investigation under the Nursing Act and a class action suit was brought by some residents and their families.[18] In Ontario, the police investigated allegations of abuse in two facilities, and an internal investigator from the Ministry also investigated.[19]

- In relation to medications, in 2003/2004 the news media reported concerns about increases in the numbers of adverse drug reactions experienced, particularly by children, and allegations that Health Canada is not appropriately monitoring and acting upon concerns.[20]
- In relation to medical research, James Dent died while participating in gene therapy research in Toronto.[21] Commentators have expressed concerns about whether current systems that monitor the conduct of research are sufficient to ensure the safety of research participants.[22]

At an international level, safety concerns relating to the delivery of health services have also been highlighted. While it is not possible, because of space constraints, to list all of the events that led to public concern about the safety of care internationally, the following list provides a sense of the concerns.

In the United Kingdom:

- A Public Inquiry was conducted into the quality of care and treatment provided to thousands of children who underwent pediatric cardiac surgery at the Bristol Royal Infirmary from 1984-1995.[23]
- A Public Inquiry was held (2000-2005) into the conduct of Dr Harold Shipman, a family practitioner, who was convicted of murdering 15 patients and is suspected to have murdered 215 patients in total.[24]

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[18] Gyslaine Desrosiers, "Recognising the Importance of Long-term Care" (2004) March/April Perspective Infirmére 10, online: OIIQ <http://www.oiiq.org/uploads/periodiques/Perspective/vol1no4/editoA.pdf>

[19] James McCarten, "Union Calls for Public Inquiry into Abuse at Brantford, Ont., Nursing Home", *Canadian Press* (12 February, 2004) online: <http://www.medbroadcast.com/channel_health_news_details.asp?news_channel_id=1000&news_id=3337&channel_id=1001&relation_id=0>.

20 "Faint Warning: Three Case Studies" *CBC Radio* (2004) online: CBC <http://www.cbc.ca/news/adr/personal/>, Paddy Moore, "From Coloured Tabs to Computerized Signals: How Canada Tracks Dangerous Drugs" *CBC News* (17 February 2004), online: CBC <http://www.cbc.ca/news/adr/>, "Sharp Increase in Children Hurt by Prescription Drugs" *CBC News* (17 February 2004) , online: CBC <http://www.cbc.ca/stories/2004/02/17/drug_reaction040217>. For a compilation of stories reporting concerns about the monitoring of adverse reactions to approved drugs refer to online at health coalition <http://www.healthcoalition.ca/drugs-media.pdf>.

[21] Jocelyn Downie & Fiona McDonald, "Revisioning the Oversight of Research Involving Humans in Canada" (2004) 12 Health Law Journal 159; Josephine Johnston & Françoise Baylis, "What Happened to Gene Therapy? A Review of Recent Events" (2004) 4 Clinical Researcher 11 and Jocelyn Downie, "Contemporary Health Research: A Cautionary Tale" (2003) Health Law Journal, Special Edition 1.

[22] *Ibid*.

[23] U.K., The Bristol Royal Infirmary Inquiry, *The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol*, (Norwich: The Stationary Office Limited, 2001), online: The Bristol Royal Infirmary Inquiry <http://www.bristol-inquiry.org.uk/>.

In New Zealand:

- A Royal Commission of Inquiry was convened in 1988 to investigate allegations that doctors at the National Women's Hospital had, for research purposes, not treated women who presented with carcinoma *in situ*, many of whom subsequently developed invasive carcinoma unnecessarily and some of whom died.[25]
- A Ministerial Inquiry was convened in 2000 to investigate allegations of under-reporting of cervical smears in the Gisborne region as a result of allegations made about the competence of the pathologist in that region.[26]
- In 2001 the Health and Disability Commissioner investigated the treatment provided to a psychiatric patient who, within 24 hours of his discharge from Invercargill Hospital, murdered his mother.[27]

In Australia:

- The Health Care Complaints Commission (New South Wales) issued a report in 2003 on the Campbelltown and Camden Hospitals suggesting that the hospitals and the administration systems in those hospitals needed significant reform. Four nurses had alleged questionable patient care, disregard for quality and safety, and an indifferent administration. The Minister of Health from New South Wales suspended two doctors and another nine were referred to the NSW Medical Board. Disciplinary proceedings were commenced against four administrators. Nineteen deaths examined in the H.C.C.C. report were referred to the State Coroner. The South West Area Health Board, that was ultimately responsible for the two hospitals, was dissolved.[28] There has since been a special parliamentary inquiry which reached the conclusion that there was a cover-up that extended to the Minister of Health.[29]

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[24] U.K., The Shipman Inquiry, *The Shipman Inquiry: Independent Public Inquiry into the Issues Arising from the Case of Harold Fredrick Shipman*, online: The Shipman Inquiry <http://www.the-shipman-inquiry.org.uk/>.

[25] N.Z., The Cervical Cancer Inquiry, *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and into Other Related Matters* (Auckland, N.Z.: Government Printing Office, 1988).

[26] Gisborne Cervical Screening Inquiry, online: Gisborne Cervical Screening Inquiry <http://www.csi.org.nz/>.

[27] Health and Disability Commissioner, N.Z., *Southland District Health Board Mental Health Services February - March 2001* (Wellington, N.Z.: Health and Disability Commissioner, 2002) online: HDC <http://www.hdc.org.nz/files/pagepublications/other_southlandreport.pdf>.

[28] Martin B Van Der Weyden, "The 'Cam Affair': An Isolated Incident or Destined to be Repeated?" (2004) 180:3 M.J.A. 100 online: Medical Journal of Australia <http://www.mja.com.au/public/issues/180_03_020204/van10893_fm-1.html> (date accessed 20 May 2004.)

[29] "Damning Findings in NSW Health Inquiry" *Australian Associated Press* (24 June 2004) online: Fairfax <http://www.smh.com.au/articles/2004/06/24/1088046209784.html>.

- There have also been high profile inquiries into the Canberra Hospital (2003) in Australian Capital Territory and the King Edward Memorial Hospital (1999) in New South Wales.[30]

In the United States:

- The plight of 17-year-old Jessica Santillan who, whilst undergoing heart and lung transplant surgery, received organs of the wrong blood type and subsequently died received international attention in 2003.[31]
- Betsy Lehman, a health reporter for the Boston Globe, died in 1995 of cardiotoxicity after she received an overdose of chemotherapy medications. Her death and the others that preceded and followed it provoked significant investments by a number of players in the health care system into implementing systems to reduce medication errors.[32]

Beyond the publicity garnered by these events empirical evidence also suggests that members of the public have a legitimate reason for concern about their concern about safety and quality in the Canadian health system.

The Evidence

Incidence

It is difficult to quantify with any certainty just how many adverse events occur in the health system. A number of countries (including Canada) have undertaken studies to assess the levels of unsafe acts within acute hospitals in each country (see Table 1). However, comparisons of these findings must be approached with caution due to differences in study methodology and in the health system in each country.

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[30] T. Faunce & S. Bolsin, "Three Australian Whistleblowing Sagas: Lessons for Internal and External Regulation" (2004) 181:1 Medical Journal of Australia 44.

[31] "Girl Tops Transplant list after error" *CNN* (19 February 2003) online: CNN <http://www.cnn.com/2003/HEALTH/02/18/transplant.error/> and Karen Frush, "Organizational Change in the Face of Highly Public Errors II. The Duke Experience" AHRQ Morbidity & Mortality Rounds on the Web (May 2005), online: AHRQ <http://www.webmm.ahrq.gov/perspective.aspx?perspectiveID=4>.

[32] James B Conway & Saul Weingart, "Organizational Change in the Face of Highly Public Errors I The Dana Faber Cancer Institute Experience" AHRQ Morbidity & Mortality Rounds on the Web (May 2005), online: AHRQ <http://www.webmm.ahrq.gov/perspective.aspx?perspectiveID=3> www.medicalerrors.com,.

Table 1 – Unsafe Acts in Hospitals – Studies from Selected Countries

Study#	Date	Adverse Event Rate	Death or Permanent Disability Rate*
United States of America (Harvard Medical Practice Study)[33]	1991	3.7%	0.7%
Australia (Quality in Australian Health Care Study)[34]	1995	16.6% (50% preventable)	3%
United Kingdom (Vincent *et al.*)[35]	1999-2000	11.7% (50% preventable)	1.6%
Denmark (Schioler *et al.*)[36]	1998	9% (40.4% preventable)	
New Zealand (Davis *et al.*)[37]	2002	12.9%	2%
Canada (Baker *et al.*)[38]	2004	7.5% (37% preventable)	0.66% (deaths)

These studies use different methodologies so comparisons must be approached with caution.
* Adverse events may not always be a causal or contributory factor in these cases. Patients may die or be permanently disabled from disease progress, rather than as a result of an adverse effect.

The information set out in Table 1 provides an estimation of the extent of the problem in the acute care setting in the countries studied in this report but there has been little or no examination of the extent of unsafe acts in other care settings. For example, the levels of unsafe acts in primary care, public health, mental health services and non-acute institutions have only been studied in a limited fashion. The relative commonalities in the results in table 1 suggest that patient safety is a significant issue in all health systems, certainly in regards to the delivery of inpatient services, and that the levels of unsafe acts are unacceptably high. In real terms, 9,250 to 23,750 Canadians are estimated to die each year as a result of unsafe care and treatment and many thousands more are physically injured.[39]

In addition, the Commonwealth Fund International Health Policy Survey found that one in four Canadians with health problems reported a medical or medication error in the past two years, with the majority stating that the error had caused serious health problems.[40]

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[33] T.A. Brennan *et al.* "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study I" (1991) 324:6 N. Engl. J. Med. 370.
[34] R. Wilson *et al.*, "Quality in Australian Health Care Study (1996) 164:12 Med. J. Aust. 754.
[35] C. Vincent, G. Neale, & M. Woloshynowych, "Adverse Events in British Hospitals: Preliminary Retrospective Record Review" (2001) 322:7285 BMJ 517, erratum in: (2001) 322:7299 BMJ1395.
[36] T. Schioler *et al.*, Danish Adverse Event Study "[Incidence of Adverse Events in Hospitals. A Retrospective Study of Medical Records]" (2001) 163:39 Ugeskr Laeger 5370.
[37] P. Davis, *et al.*, "Adverse Events in New Zealand Public Hospitals I: Occurrence and Impact" (2002) 115:1167 N.Z. Med. J. U271.
[38] G. Baker, *et al.* "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada" (2004) 170:11 C.M.A.J. 1678.
[39] *Ibid*.
[40] The Commonwealth Fund, *The Canadian Health Care System supra* note 14.

Costs

The provision of health services is a costly exercise – the percentage of the GDP allocated to the funding of health services was approximately 9.6 percent in 2002 – well before the recent increases in the federal contribution.[41] Some of these costs are incurred in addressing problems that are preventable, such as unsafe care and illness caused by 'lifestyle'. The analysis of the incidence of unsafe care, described above, suggests that some episodes of unsafe care are preventable and consequently that the costs associated with unsafe care can also be minimized. This is perhaps in contrast to 'lifestyle' related illnesses where the correlation is less directly true.

At a fiscal level unsafe care is expensive. Table 2 sets out some estimates of the monetary burden of unsafe acts in the health system.

Table 2 – Estimated Costs of Unsafe Care in Health Systems

Country	Direct Costs# per year	Total Costs* per year
United States (Thomas)[42]	U.S. $8.5- 14.5 billion	U.S. $17-29 billion
United Kingdom (D.H.)[43]	£2 billion (hospital days)	
Australia (Task Force)[44]	A$867 million (hospital days)	
Australia (APSF)[45]		A $2 billion

* Total national costs for preventable unsafe acts (including lost income, lost household production, and disability and health care costs).
# Health care costs for preventable unsafe acts.

To place these figures in context, total spending on the health sector in England in 2004 was £69,369 billion[46] so if the direct cost of unsafe care is £2 billion this is approximately three percent of the total health budget. This figure does not account for the total costs of unsafe care including lost income and productivity which may double the costs to six percent of the total health budget in England.

Costs are not experienced solely at the level of government budgets – there are also very real costs, fiscal and otherwise, experienced by individuals, patients, friends and families, health providers and communities.

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[41] 2002 figures from the World Health Organization, *Canada* online: WHO <http://www.who.int/countries/can/en/>.
[42] E. Thomas, D. Studdert *et al* "Costs of Medical Injuries in Utah and Colorado" (1999) 36 Inquiry 255.
[43] U.K. Department of Health, *An Organisation with a Memory*, (London: Department of Health, 2000).
[44] Task Force on Quality in Australian Health Care, *Final Report of the Task Force in Australian Health Care* (Canberra: Department of Health and Aging, 1996).
[45] Australian Patient Safety Foundation, *Iatrogenic Injury in Australia* (Canberra: Department of Health and Aged Care, 2000).
[46] HM Treasury (U.K.) *2004 Spending Review* (London: HM Treasury, 2004) online: HM Treasury <http://www.hm-treasury.gov.uk/media/801/75/sr2004_ch8.pdf>.

An individual patient may die or suffer increased pain, disability and psychological, emotional and spiritual harm as a result of unsafe care. The outcomes of unsafe care may impact on that individual's ability to care for his or her family, his or her contribution to the community, and his or her ability to work. It may result in increased costs for the individual, such as childcare, rehabilitation, time off work, transportation costs, legal fees and other associated costs. Families may have to go through a grieving process if a family member dies as a result of unsafe care. Families may need to provide supportive home-based care for injured family members or to support an individual to resolve, if possible, any psychological, emotional or spiritual harm. Families may incur extra costs such as time off work, accommodation, transportation costs and other associated costs. Family members may also feel guilt that they did not do enough to prevent the unsafe care from occurring, and may feel reluctant to access health care services in future. While the reality is that many of the factors listed above are consequences of illness and death, in the situation where an individual has received unsafe care these consequences were unnecessary and could have been prevented.

Health care providers may experience shame, guilt, and depression when care is provided in an unsafe manner, whether or not their actions contributed to the unsafe care. Health care providers' ability to work may be impaired, their personal life affected, and they may face additional expenses such as legal fees.

The community also bears the costs of unsafe care. The community is affected by the strains placed on individuals and their families. Workers may have to work longer hours to cover absent colleagues, teachers may have to deal with the various expressions of children's stress if a parent, sibling or other family member has died or is ill and the community feels the loss of volunteers. On another level, the community must bear the productivity losses felt by the economy and the direct fiscal costs of harms resulting from the provision of unsafe care must be borne ultimately by the community through the health or social systems.

Unsafe care therefore results in significant *preventable* costs to the health care system and also in significant *preventable* direct costs - fiscal, emotional and psychological to name but a few - to individuals, their communities and to the state. Minimizing the occurrence of unsafe care could result in significant savings that could be directed at the provision of additional health care services or other social supports, such as housing or income replacement that could improve health.

The Concept

The approach to patient safety is evolving in literature and also, although perhaps more slowly, in practice, policy and in law. Traditionally, patient safety has been addressed through a person-centered approach which focuses on apportioning responsibility to individuals that are seen to have caused the unsafe act. This is reflective of the structures of health systems in the past where individual health professionals provided services largely independently of one another or in simple teams or organizations. The increasing

complexity of the provision of services is reflected in the complex organization structures that surround the provision of care and the increasing technological innovations that also make care and treatment more complex. Environment therefore is an increasing influence, at times positive but sometimes negative, upon the manner in which health services are delivered. Accordingly, modern approaches to patient safety are increasingly system-centered, however, most agree that at times it is appropriate for individuals to be held accountable and so the person-centered approach will always have a role in the governance of patient safety.

Person-centered approach

A person-centered approach to patient safety is intuitively attractive as it assigns clear responsibilities and therefore accountabilities to an individual(s). It satisfies societal needs to identify a *person*(s) to blame for the harms caused. In contrast, there is a sense when systems are blamed that 'they are going to get away with it' because a faceless entity is identified with possibly amorphous accountabilities.

A person-centered approach is said to capture the three faces of individuals who may cause harm in the delivery of health services.

1. Human error (error)

This approach suggests that individual(s) cause errors. Reason, the leader in this field, primarily focuses on the psychological precursors of human error, such as inattention, forgetfulness, and carelessness.[47] However, competence can also be a cause of error – sometimes planned actions fail due to a lack of skill or competence, and, likewise, sometimes incorrect plans are made.

2. Violation

Violation is where there has been a deviation from standards, rules, or safe operating procedures.[48]

3. Sabotage

Sabotage is where an individual intends the act *and* the harm that results; in short the individual's actions are malicious.[49] Individual health providers may, very rarely, abuse their position to harm patients. The ultimate example of this is Dr. Harold Shipman, a general practitioner from Britain, who was convicted of murdering 15 patients through the use of lethal injections of an opiate or sedative while providing a health service. A public inquiry concluded that Dr. Shipman murdered a minimum of 215 of his patients.[50] The Honourable Mr. Justice Forbes said when sentencing Dr. Shipman, "None of your victims realized that yours was not a healing touch. None of them knew that in truth you had brought her death, death which was disguised as the caring attention of a good doctor."[51] Another example of sabotage is Dr. Morgan Fahey, a general practitioner from

[47] J. Reason, *Human Error* (Cambridge: Cambridge University Press, 1990).
[48] Canadian Patient Safety Dictionary *supra* note 6 at 27.
[49] *Ibid* at 27.
[50] Shipman Inquiry, *supra* note 24.
[51] The Honourable Mr. Justice Forbes when sentencing Shipman on 31st January 2000.

New Zealand, who, during the course of examinations and treatments, abused female patients. He was convicted of 13 charges of sexual assault, including one charge of rape.[52]

The person-centered approach is the dominant tradition within the academic literature on patient safety and has heavily influenced the use and design of legal instruments in the health sector. Legal instruments used to address person-centered safety issues are aimed at individuals rather than situations or systems and fall within the 'compliance' or control mode of regulation.[53] Examples include: the criminal law; tort law; professional regulation; and regulatory standards that purport to guide individual behaviour. Person-centered legal instruments create clear frameworks for individual accountability, which is important as individuals should most often be held accountable for their actions or omissions.

However, critics argue that a person-centered approach isolates unsafe acts from their context. The healthcare system is a complex environment where individual actors, organizations and technologies intersect to provide a continuum of care. Even in a case which seems self-evidently person-centered, such as Dr. Shipman's, his actions were framed by the system in which he worked. Dr. Shipman was able to murder patients in the course of his medical practice because he could access high quantities of so-called 'controlled drugs' without being monitored. Whilst the legal process focused on holding Dr. Shipman accountable for his actions, broader safety related systems issues could not be ignored. A person-centered approach does not always recognize the complexities of systems and failures. In addition, a focus on 'naming, shaming and blaming' an individual is said by practitioners, and more latterly researchers, to inhibit open discussions about episodes of unsafe care and therefore an ability to learn from these episodes to facilitate the future provision of safe care.[54]

Systems Approach

The so called systems-centered approach to patient safety is an emerging one in the patient safety literature and is influential in more recent policymaking in the health care sector. This approach places patient safety issues in a more complex framework. Individual failures are viewed in their broader context, so they are regarded as just one part of a picture. The premise is that all humans are fallible and that personal failures or abuses are inevitable but blame should be avoided to facilitate learning. This systems approach recognizes that actions or omissions of an individual are framed by upstream systemic factors. At an organizational level, these systemic factors can include an organization's strategy, culture, and its attitude towards risk and uncertainty. There are

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[52] A. Horwood & J. Corbett, "Fahey- Sexual Predator in a White Coat" *New Zealand Herald* (2 June 2000) online: The New Zealand Herald <http://www.nzherald.co.nz/storydisplay.cfm?thesection=news&thesubsection=&storyID=138943> [date accessed 5 May 2004].

[53] Christopher Newdick, "N.H.S. Governance after *Bristol*: Holding on, or Letting Go?" (2002) 10:2 Med. L. Rev. 111 at 117.

[54] See for example, The Bristol Royal Infirmary Inquiry, *supra* note 23, J Bryan Sexton, Eric J Thomas, & Robert L Helmreich, "Error, Stress, and Teamwork in Medicine and Aviation: Cross Sectional Surveys" (2000) 320:7237 B.M.J. 745, Institute of Medicine. *To Err supra* note 8.

also external systemic drivers that shape safety and, more broadly, quality, such as regulation and legislative action and economic and other incentives/barriers including the norms and values of health professionals.

A systems approach recognizes that the human condition of fallibility cannot be changed, although it may be limited by changing the environments and conditions under which people work. It recognizes that most individuals or organizations that operate in circumstances where harm can result from their acts tend to develop barriers, defenses and safeguards to prevent harm. However, human elements can weaken these defenses by active failures and latent conditions.[55] Active failures are unsafe acts committed by individuals who directly provide care. Latent conditions arise from strategic decisions made by designers, builders, policy-writers and managers, who may create conditions that can translate into an environment that creates conditions that might provoke unsafe care, for example, a requirement that physicians work 24 hour shifts. Under the systems approach, when an unsafe act occurs, the important issues are not who made the error but how and why the defenses failed and what factors helped create the conditions in which the unsafe acts occurred. A systems approach to patient safety appears to us to put safety into a quality context.

Critics suggest that the systems approach potentially may limit or obscure legitimate individual or organizational accountabilities. At times it is appropriate that an individual(s) or organization(s) should be held accountable for unsafe acts and it is important that this aspect not be lost when focusing on systems factors. Proponents argue that accountability is important, particularly for egregious cases, but that there should not always be an assumption that an individual's failure is the principal or only cause of harms resulting from unsafe care, indeed they suggest that focus on individuals should be placed in the context of a system that may have failed at many points.

Both approaches to the governance of patient safety are currently being used. Patient safety related legislative frameworks are seeking to find a balance between demands for accountability, learning, and also restoration for the patient and the health provider.

One of the significant issues relating to the use of legal instruments in regard to patient safety is there is often little or no evidence that the mechanisms put in place by law are actually effective in improving patient safety. First, it is rare that the impacts of law on outcomes are studied. Second, even if they are studied many of the newer patient safety initiatives are too recent to provide reliable empirical data, although anecdotal evidence is often supportive. Third, the law of adverse events dictates that although a mechanism may appear to work in that one particular outcome or indicator improves, the consequences of the change may throw out of balance another aspect of the complex environment in which healthcare is provided thus negatively impacting patient safety outcomes in other areas. Fourth, what may work well in one context or culture may not work well in another. It is however clear that the use of legal instruments as part of the process of the governance of patient safety can be an effective tool in that it can improve accountability and transparency. The challenge of policy-making in this area appears to

[55] Reason, *supra* note 47.

be to identify and encourage the development of initiatives that will have a real and sustained impact upon patient safety but at the same time balance this with mechanisms that allow individuals and organizations to be held accountable when this is appropriate.

Governance, Legal Instruments, and Patient Safety

'Governance' can be defined as "the sum of the many ways individuals and institutions, public and private, manage their common affairs".[56] Central to the concept of governance is the recognition that government is no longer, if it ever was, the sole actor in the policy sphere – there is a complex array of public and private actors, at the individual, local, regional, national and international level. These actors pursue a variety of policy objectives through the use of a dense mosaic of policy tools. Each actor plays an important role in the management of common issues of importance. There is a range of policy tools available for use, including legal instruments, many of which place public agencies in complex, interdependent relationships with a host of third party actors.[57]

Government has somewhat asymmetrical relationships with the other actors that shape policy and practice due to the government monopoly over the process of establishing law.[58] Law grants the government power to impose top-down initiatives in respect of particular problems. However, many problems are too complex for a top-down solution, even if one were possible. Although the state may take a leadership position in relation to a certain issue, it can often most successfully work in collaboration with other individuals, agencies and groups to achieve a desired outcome. After all, the effectiveness of laws and legal frameworks can be undermined or defeated without the support of the governed.[59] Within this interconnected network of policy actors, government plays a role which at its most basic is to establish an "interlocking network of public powers that regulate and guide action in a relatively consistent way, providing minimum standards of conduct and relief from harm."[60] A focus of this research is therefore to examine the limits of the state to recognize, define, respond to, to have

[56] Kernaghan Webb, "Sustainable Governance in the 21st Century: Moving Beyond Instrument Choice" in Pearl Eliadas, Margaret Hill & Michael Howlett, *Designing Government: From Instruments to Governance,* (Montreal & Kingston: McGill-Queens University Press, 2005).
[57] L. Salamon, "The New Governance and the Tools of Public Action: An Introduction" in L. Salamon ed. *The Tools of Government: A Guide to the New Governance* (Oxford: Oxford University Press, 2002) at 3.
[58] R. Rhodes, *Understanding Governance: Policy Networks, Governance, Reflexivity and Accountability,* (Buckingham: Open University Press, 1997).
[59] Studies have also indicated that health providers (and other non-health related actors), on occasion, have acted to subvert laws because they either do not agree with them, there is a perception that they create too much work or that they are impractical. This suggests that a greater degree of consultation and agreement is required before legal instruments are used, or alternatively that stronger enforcement mechanisms are required. See for example, Jill Peay, & N. Eastman, eds. *Law without Enforcement: Integrating Mental Health and Justice* (Oxford: Hart Publishing, 1999).
[60] P. Hirst, & G. Thompson, "Globalization and the Future of the Nation State" (1995) 24:3 Economy & Society 408.

available, and to use legal instruments that are necessary and most appropriate to take action in response to a defined problem.[61]

Patient safety is an issue upon which there seems to be general consensus amongst all policy actors in the various international health systems that some action is necessary. Indeed, in the last five to fifteen years there has been a significant engagement with the issue by policy actors, with what success we are only just beginning to find out. Policy actors at all levels of international health systems have used a variety of policy tools to address patient safety issues. This project focuses on governmental decision-making in relation to choices around whether or not to use legal instruments and what specific ones to use and why. It bears repeating that governments' use of legal instruments is only a part of a broader governmental governance strategy and, similarly, is only a part of a broader patient safety governance structure driven by a variety of non-government actors using a variety of policy tools.

Choice of Policy Tools

Policy objectives are pursued through the use of a dense mosaic of policy tools, such as the use of law, other forms of social regulation (e.g. guidelines and standards), contract, provision of inducements and so on.[62] The process of choosing a particular policy tool to address a specific issue once identified is a complex and not well understood process. The process is influenced by the views, actions, and responsiveness of the other actors within the polity. It is clear from some of the countries studied that government intervention is often considered only after other policy actors have failed to either recognize the problem or effectively address it, or when there is a perception to this effect, so government steps in to compensate for failure. Choice of instrument type may also be affected by the nature of government's role in respect of a particular enterprise. For example, government may be more likely to intervene more directly and aggressively, when, in addition to having a responsibility to provide Hirst and Thompson's "minimum standards of conduct and relief from harm",[63] it also plans, funds, owns and operates a service. A service that is successful and safe in operation is moreover central to the public interest as defined in each country.

The Actors

The choice of instrument type also determines how directive the government chooses to be in its intervention and how it characterizes its relationship with other policy actors or networks. The development and maintenance of a public health system in Canada involves a complex array of public and private actors, at individual, local, regional, national and international levels. Governments play a leadership position in relation to the establishment of the public health system, but work in collaboration with other individuals, agencies and groups to achieve the desired outcome. The Canadian health

[61] C. Tuohy, "Agency, Contract and Governance: Shifting Shapes of Accountability in the Health Care Arena" (2003) 28:2-3 J. Health Pols Pol & Law 195 at 202.
[62] Salamon, *supra* note 57 at 3.
[63] Hirst & Thompson, *supra* note 60.

system, and the health systems in other international jurisdictions, continues to depend upon the interdependent relationships between governments, government agencies, health care institutions, health professionals, professional and institutional associations, interest groups, insurers, consumers, and the public, to provide but an incomplete list. Governance choices are therefore often constrained or influenced by the nature of inter-relationships between policy actors. To use Tuohy's typology, a health system may be:[64]

- a hierarchically, geographically organized system under the aegis of the state (for example the U.K. and New Zealand) with a high level of government involvement in governance but some deference accorded to physicians. Due to its hierarchical nature, this model enables a model of governance that favours top down control by government;
- a system weighted towards private finance and the market (for example, the U.S.). Reliance on the market enables a model of governance where government focuses on the use of contracts, inducements and declarations, with some concern about remedying asymmetry of information;
- a system that gives predominant weight to medical professional and collegial mechanisms (for example, Canada). This model may favour governance choices that are collaborative in nature and the use of contracts, agreements and partnerships.

As Rhodes notes, there are clearly limits and constraints on central intervention, whether through the use of legal instruments or not, because of the many interdependencies with which policy domains are riddled[65] and the degree of deference accorded some policy actors, such as physicians, may influence instrument choice.[66]

The Constitutional Framework

The nature of the relationships between interdependent networks of policy actors will not be the only factor to effect instrument choice. Constitutional structures may also impose barriers upon the government's choice or ability to use policy instruments. In three of the countries studied, Canada, the United States and Australia, governmental decisions in relation to the use of legal instruments occur at federal and provincial levels. As Hogg states in respect of Canada:[67]

> Health is not a single matter assigned by the Canadian constitution exclusively to one level of government. Like inflation and the environment, health is an 'amorphous topic' which is distributed to the federal parliament or provincial legislatures depending on the purpose and effect of the particular health matter at issue.

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[64] Carolyn Hughes Tuohy, *Accidental Logics: The Dynamics of Change in the Health Care Arena in the United States, Britain and Canada*, (New York: Oxford University Press, 1999).
[65] Rhodes, *supra* note 58.
[66] See for example, Tuohy, *Accidental Logics supra* note 64.
[67] P. Hogg, *Constitutional Law of Canada* [4th ed.] (Scarborough, Ont.: Carswell Publishing, 1997) at 445.

Federal and provincial laws often interact with each other in complex ways.[68] So in addition to negotiating with non-governmental actors, governments in these nations must also negotiate intra-governmentally with a number of governments and government agencies. This has been noted as a significant challenge in respect of ensuring consistency and continuity of outcomes across countries.

In the three other countries studied, Denmark, Britain and New Zealand, governance decisions in relation to legal instruments occur at the national level requiring less intra-government negotiations, although some are still required.

The Regulatory Context

In some countries the nature of the state's role in governance has been changing. The phrase 'the regulatory state' was first developed by Majone[69] and has been adopted by others.[70] From the introduction of the welfare state until the later part of the 20th century, in many states the role of government was relatively all-encompassing with government acting not merely as a regulator, but also as a service provider, job creator, property owner and employer. In the later part of the 20th century, new models of economic thought became dominant, particularly the so called New Public Management (NPM), and became influential. The NPM emphasizes the centrality of the citizen consumer; standards and measures of performance; results based accountability; private sector styles of management; purchaser/provider splits and the use of alternate service delivery mechanisms; de-bureaucratization; devolution; the supremacy of the market and the virtues of competition; hands-on professional management; and discipline and parsimony in resource use.[71] Due to the de-regulatory rhetoric associated with the NPM, one of the key planks of the NPM platform was regulatory reform. Market competition was encouraged through a movement away from command and control models of regulation towards the use of alternate regulatory frameworks that were felt to be more flexible and market friendly. The state's retreat from the use of command and control regulation also opened a more expansive role for government focused on oversight of private and public operations. The transfer of public functions to private actors also transferred the management of public risks to private actors. Risks were also managed by government agencies, independent or otherwise, which were often in interdependent relationships with the private sector and operated under private sector principles. Governments recognized that the market does not always respond appropriately to managing and limiting public risks so some regulatory intervention by government to protect the public interest is therefore required. Thus regulation in its broadest sense increased, hence the regulatory state. Internationally there is a large degree of variability in the degree to which countries imported these principles into the governance of the public sector. An

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[68] T. Jost, "Health Care Rationing in the Courts: A Comparative Study" (1997-1998) 21 Hastings International & Comparative Law Review 639 at 640-644. [Jost, Rationing].

[69] G. Majone, "The Rise of the Regulatory State in Europe" (1994) 17 West Eur. Pol. 77.

[70] See for example: Michael Moran, "Understanding the Regulatory State" (2002) 32 Brit. J. Pol. Sci. 391; J. Braithwaite, "Accountability and Governance under the New Regulatory State" (1999) 58:1 Aus. J. Pub. Admin. 90; Symposium, "Getting Beyond Cynicism: New Theories of the Regulatory State" (2002) 87 Cornell L. Rev. 267; C. Scott, "Accountability in the Regulatory State" (2000) 27:1 J.L. & Soc'y. 38.

[71] See for example, N. Lewis, "Responsibility in Government: The Strange Case of the United Kingdom" (1995) 1:3 Eur. Pub. L..

examination of the differences in the degree of the uptake of these principles within the health systems of each country may point to differences in the regulatory state that may shape and condition responses to the choice of policy instruments used.

The regulatory state is a state that is conditioned to respond through regulatory means, often through the use of law, although not exclusively, to problems relating to the management of risk. Many states are changing the manner in which they use law, particularly in regard to the governance of certain sectors. Some of these states are moving from traditional self-regulatory models that devolve responsibility for management of the common affairs of a sector or professional group, and the responsibility for providing standards for conduct and relief from harm to that group or sector. These states are turning to so-called meta-regulation or in other words are moving to regulate the regulators. Others are moving or have moved from self-regulatory models to what could be called professional regulation – where the state reclaims in whole or in part some or all of the functions of previously self-regulating bodies. The state now exercises these functions through the use of a variety of quasi-independent government bodies. Changes in the governance framework around patient safety, particularly changes involving the use of policy instruments, must be viewed not in isolation but as part of a broader development in the way government thinks about its governance role and responsibilities.

The Problem Context

How a particular issue is conceived may also affect policy instrument choice. Significant legal reforms to establish a more rigorous governance framework for patient safety have occurred in countries with histories of widely publicized and publicly investigated scandals involving unsafe care. Absent such issue-related public pressure to enact top-down reform, governments may choose less intrusive policy instruments to work collaboratively with other policy actors to affect change.

Use of Legal Instruments

Legal instruments are a relatively common tool used by government in the governance of the health system. In every country there are complex webs of legal instruments which establish a framework within which services are provided. Legal instruments govern the financing, expenditures, functioning and structure of social insurance or national health services, the licensing and monitoring of professionals and institutions, the protection of public health, and the funding of health care research and education, to name but a few.[72] More specifically in regard to patient safety legal instruments can empower individual health professionals, organizations (such as the Colleges of Physicians and Surgeons) and institutions to take action to improve patient safety.[73] Second, they can provide a call for action from an external agency which requires a response or else sanctions are imposed.[74] Third, they can require all institutions, organizations and professions to make minimum

[72] Jost, Rationing *supra* note 68 at 640.
[73] Institute of Medicine. *To Err supra* note 8 at 19.
[74] Jost, Rationing *supra* note 68 at 640-644.

investments in safety and quality[75] creating a system where all persons, wherever they might live in a country or province, have health services provided safely. Fourth, they can create oversight systems to police individuals, professions, organizations and institutions. Fifth, they can empower members of the public to demand safe care. Sixth, they can provide a check to ensure that a patient's fundamental human and constitutional rights, such as autonomy, are not undermined or ignored during the process of establishing and maintaining safe systems. Seven, law can balance the need to create environments that facilitate the open discussion of and learning from episodes of unsafe care with a patient's right to know information about his or her treatment and with the demands of individuals and the public for accountability for egregious acts. However, it is also important to note that regulation or legislation can create disincentives for individuals, professions, organizations or institutions to practice safely, such as laxly enforced or conflicting standards.

Administrative agencies created by law also play a role in health care systems. Administrative agencies may, amongst other functions, regulate professionals and institutions, manage public purchasing decisions and provision and make determinations in respect of individual patients. Agencies issue rules and adjudicate disputes in respect of health care relationships.[76] The courts in most countries oversee health care relationships by reviewing and enforcing administrative decisions, protecting those who suffer criminal or tortious harms and by interpreting and enforcing health-related legislation, regulation and contracts.[77]

Coerciveness

Legal instruments can also be considered not just in terms of what effect they are meant to achieve but also within a continuum of coerciveness. The Bemelmans-Vidac typology is an example of a typology that considers the degree of coerciveness attached to each instrument.[78] The typology considers instruments as being:

- sticks (in other words "you must comply or face penalties"). Sticks are usually expressed as commands involving mandatory participation combined with monitoring and enforcement mechanisms;
- carrots (in other words "we'd like you to do this and if you do we'll do something nice for you"). Carrots are usually expressed as some form of scheme, typically involving the use of such tools as contracts and tax incentives involving inducements;
- sermons (in other words "it's the right thing to do"). Often this is expressed through the creation of government agencies with educative or research functions, but also may just be a declaration of the level of importance of the issue, for example, government awards for patient safety initiatives or a declared patient safety week.

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[75] *Ibid*.
[76] *Ibid*.
[77] *Ibid*.
[78] Marie-Louise Bemelmans-Vidac, Ray Rist & Evert Vedung, eds., *Carrots, Sticks and Sermons: Policy Instruments and Their Evaluation*, (New Brunswick, N.J.: Transaction Publishers, 1998).

Often government uses a mix of legal instruments throughout the coercive spectrum to address identified patient safety needs. The degree to which governments choose to use a coercive tool depends on the factors discussed earlier – namely the degree of interdependency with other actors in the health system which may in turn be influenced by the traditional structures of the health systems and the design of constitutional systems.

Evaluation

We evaluated the legal instruments used in each country and sector against the following criteria.

1) Effectiveness.
This has to be the most basic criteria for evaluating the success of legal instruments. If an instrument does not achieve its intended outcomes, then it may be of little value.

2) Efficiency
Efficiency measures results against costs. The paradox is of course that the most effective instrument may not be the most efficient one.

In relation to both effectiveness and efficiency, there are some barriers to gauging the respective effectiveness and efficiency of legal instruments used in respect of patient safety. First, legal instruments often have multiple, at times conflicting or uncertain, outcomes which makes evaluation more complex. Second, many patient safety initiatives that are expressed through the use of legal instruments are relatively new; those that are not so new, such as professional regulation, may have been recently substantially reformed. Given the relatively recent emergence of some of these initiatives there is often very little empirical data as to effectiveness or efficiency, although there may be much anecdote. Even in the other non-health related sectors that were reviewed, there has often been little examination of the effectiveness or efficiency of the initiatives and of the legal instruments used. Third, legal instruments must also be reviewed as part of an integrated governance framework in respect of a particular issue. Effectiveness may depend, at least in part, upon the interactions with other instruments in that framework. Fourth, it is important to note that the effectiveness and/or efficiency of a particular initiative expressed through a particular form of legal instrument may not be replicable in another country or sector, due to differences in culture. Cultural differences can be crucial to the success or failure of legal instruments and legal frameworks.

3) Equity
Equity is a third crucial criterion against which legal instruments can be measured. One of government's most important roles is to ensure individuals and groups are treated fairly and equally. This criteria is not always applicable to some of the instruments that have been examined but is an important underlying value that must inform any analysis.

4) Transparency

Transparency is of key import as it enhances democracy by correcting asymmetry of information between the public and its agent, government. It has a valuable educative function and so enables effective public involvement in decision-making. It also enables public accountability for actions and omissions at all levels of activity, from individuals to government. Transparency can be established through an assessment within each instrument of the accessibility of information about issues of concern and of information about processes that address these issues and how these processes function.

5) Accountability

Broadly, there are five forms of accountability for public action: (1) legal, (2) financial, (3) administrative, (4) professional, and (5) political. This concept imports conceptions of taking responsibility for actions but this can be through a process of being answerable to the public at large or to individuals, rather than necessarily being associated with blame and fault. Blame or fault is almost inevitably part of legal accountability in respect of patient safety due to the current systemic structure of malpractice suits in most countries. Again, this can largely be assessed through a scrutiny of each legal instrument.

Patient Safety Law:
From Silos to Systems

Appendix 2: Country Reports
AUSTRALIA

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William Lahey
Don Ford
Elaine Gibson
Mary Thomson
Tom Ward
Fiona McDonald
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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,

[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

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[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

[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]

[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.

Patient Safety Law:
From Silos to Systems

Appendix 2: Country Reports
DENMARK

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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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DENMARK

Denmark is a constitutional monarchy located in the Nordic region of Europe. It has traditionally functioned as a social democracy. Its present minority coalition government is considered somewhat 'right' of centre. The population of Denmark is approximately 5.4 million.

Health Care System Context

Law

In Denmark, a unified legal system was established in 1683.[1] It is a civil law system, with its civil law rules emanating from legislation or established by practice - i.e., case law or customary law; there is no civil code. Many of the principles that underlie Danish law come from Roman law.

Law is divided into public law and civil law, but the border between the two is not easy to define. Public law is characterized by a focus on general social interests, and state organs other than the courts play the major role in applying the regulations. Public law is divided into constitutional law, international law, administrative law, criminal law and the law of procedure. Civil law regulates the reciprocal relations between natural persons and legal persons through the use of torts, contracts, property, capacity, and family law, and laws regarding wills and succession.

There are laws and regulations called anordninger (regulations), bekendtgorelser (orders) or in some areas reglementer (regulations) or vedtaegter (statutory instruments). These may be supplemented by government circulars.

Health

The foundations of the Danish health care system are: a public system funded predominantly through taxes; decentralization; universal, free and equal access to health care for all; and a health care service that is of high quality, promotes efficiency, and enables free choice of providers by consumers.[2] Eighty-five percent of health care in Denmark is publicly-funded through a tax-funded social insurance scheme.[3] Taxes are collected at both the national and local level to fund the health system.

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[1] Ministry of Foreign Affairs, "Legal System," online: Ministry of Foreign Affairs <http://denmark.dk/portal/page?_pageid=374,520481&_dad=portal&_schema=PORTAL>.

[2] The Institute for the Study of the Civil Society, "Background Briefing: Health Care Lessons from Denmark," online: Civitas <http://www.civitas.org.uk/pdf/Denmark.pdf>.

[3] Ministry of the Interior and Health, "Health Care in Denmark" (Copenhagen: Ministry of the Interior and Health, 2002) at 4, online: Ministry of the Interior and Health <http://www.im.dk/publikationer/healthcare_in_dk/healthcare.pdf > [Ministry of the Interior and Health].

Health Services Delivery

The health system in Denmark is described as "a governance system of negotiated order."[4] The role of the state in the Danish health system is therefore to "initiate, coordinate and advise."[5] Responsibility for health-related legislation and overall guidance remains with the Ministry of the Interior and Health.[6] This includes legislation on the provision of health, personnel, hospitals and pharmacies, medicinal products, foodstuffs, vaccinations, pregnancy health care, child health care and patients' rights, as well as the setting of the tasks of the counties and local authorities and guidelines for the running of the health care service. However, because no national agency actually provides care, negotiations must occur between the government and the regions/local authorities to determine global budgets and national priorities.[7] National budget negotiations occurs once a year between the Ministry of the Interior and Health, the Ministry of Finance, the Association of County Councils and the National Association of Local Authorities (although much of the revenue spent on health is gathered through local, as opposed to national taxes, there is some regional redistribution and additional funds are provided by the national government). This negotiation sets the targets for the healthcare system to achieve. Central government is seen to be increasingly using these negotiations to highlight priority areas in health care and thus to influence the shape of the health care system.[8]

The National Board of Health, established in 1932, is the oldest Board of Health in the world. It is responsible for supervising health personnel and institutions, including pharmacovigilance, control of addictive medications, patients' rights, legislation on certification and licensing, forensic medicine and psychiatry, biomedicine, artificial fertilization, human genetic engineering, traffic medicine, alternative therapy, contagious diseases and vaccines. Its tasks are defined in the *Act Concerning the Central Administration of Health Care*[9] and include assisting the Minister of the Interior and Health in administering health care matters, monitoring health conditions and keeping up-to-date on current medical knowledge regarding health care, notifying the appropriate authorities when informed of violations or shortcomings in the health sector, advising the Minister of the Interior and Health on health issues, supervising health care personnel and their professional activities. Through authority granted by other legislation it also undertakes hospital planning, certification and licensing of professionals, workforce

[4] K. Vrangbaek, "Presentation to Health Policy Reform Group" (2002), cited in The Institute for the Study of the Civil Society, "Background Briefing: Health Care Lessons from Denmark," online: Civitas <http://www.civitas.org.uk/pdf/Denmark.pdf> at 3.
[5] Ministry of the Interior and Health, *supra* note 3 at 9.
[6] Signild Vallgårda, Allan Krasnik & Karsten Vrangbæk for the European Observatory on Healthcare Systems, "Health Care Systems in Transition: Denmark" (Copenhagen, European Observatory of Health Care Systems WHO Regional Office for Europe, 2001), online: European Observatory on Health Care Systems <http://www.euro.who.int/document/e72967.pdf>.
[7] Note that the county system is being phased out and replaced by regions. As of 2007, the three regions will own the hospitals, with budgets dictated by the state.
[8] The Institute for the Study of the Civil Society, "Background Briefing: Health Care Lessons from Denmark," online: Civitas <http://www.civitas.org.uk/pdf/Denmark.pdf>.
[9] See Retsinformation, online (in Danish only): Retsinformation <www.retsinfo.dk> [Retsinformation].

planning and running a number of registries and monitors risk areas. Other relevant national agencies include: the National Council on Public Health and Health Promotion; the Danish Institute of Health Technology Assessment; the National Serum Institute (Vaccines); the National Institute of Public Health; the Danish Council of Ethics; Negotiation Committee of Public Health Security; Danish Institute for Services Research and Development; the Danish Medical Research Council; the Danish Centre for Research in Environmental Medicine; the Danish Central Scientific Ethical Committee.

The National Indicator Project was established in 2000 by the Ministry of Health and the Interior, the National Board of Health, the counties and the Copenhagen Hospital Corporation, and other professional groups. It establishes quality standards, indicators and prognostic factors for six diseases; collects data, conducts audits, and publicly releases results. Participation is mandatory. It aims to assess the health system as a system, not to find scapegoats but to bring about quality improvements

The National Patient Satisfaction and Evaluation Survey was established through an agreement between the Ministry of Interior and Health and the regional councils to conduct a patient satisfaction survey each year to establish a baseline for comparison to target quality improvements. It is financed by the regions and managed by a joint group including the Ministry. The Unit for Patient Evaluation in the Copenhagen Region conducts the survey.

The National Program of Databases was established in 2000 by the regions and municipality in partnership with the National Board of Health and the Danish Medical Society. One aim is to see that all publicly funded databases live up to international standards.

The Danish Good Medical Department (DGMA) is a national quality improvement program for hospitals and primary care launched in 2000 by the regions/municipality, the County Council Society, the Ministry of the Interior and Health, the National Board of Health, and some others. It aims to develop generic standards, performance management measures and patient evaluation and satisfaction studies and follow-up activities. It is a voluntary program.

The Danish Secretariat for Clinical Guidelines was set up in 2000 to support medical societies and other health professional groups in the development of professional guidelines. From 2000-2003 it was under the auspices of the Danish Medical Society, although funded by the National Health Board through the Danish Centre for Evaluation and Health Technology Assessment. Since 1 January 2004, it is part of the Danish Centre for Evaluation and Health Technology Assessment.

The Danish Society for Patient Safety was established in December 2001 as a non-profit organization. Its primary aim is to ensure that patient safety is considered in all health care decision-making; thus, it views itself as a political force. Members of its Board represent a broad range of stakeholders, including health care professionals, patient and

research organizations, hospitals, the pharmaceutical and medical device industries, and local governments in Denmark.

The Society is funded through an annual contribution from hospitals, institutional and individual membership dues, voluntary contributions, and grants from foundations. Some of its functions are to provide advice to legislators and to stakeholders, to suggest standards for safe operation, and to develop consensus. In these ways it contributes directly to the development of legislative standards. The Society also initiates projects aiming to empower patients to take positive and assertive measures to attempt to protect their own safety.

The Ministry of the Interior and Health and the National Board of Health issued a national strategy on quality improvement and health care in 1993. The National Council on Quality Improvement in Health Care was established in 1999 to revise and further develop the strategy. A new strategy was issued in 2002. Inside the National Board of Health, a Secretariat for Quality has been established to assist with initiatives.

The primary goal of the quality strategy is to contribute to the high level of quality in terms of single health care benefits and continuity and coherence in patient pathways (i.e., disease specific standards, organizational standards and general standards). The areas of effort for the strategy are: patient influence and user involvement; patient safety; communication of knowledge and transparency in the systems; and competence development.

Within the patient influence and user involvement category, the strategy focuses on: the provision of additional written information and guidance upon treatment, care and rehabilitation so that patients can become more actively involved in treatment; patient influence upon the auditing process through the establishment of a committee to discuss audits; and patient satisfaction surveys.

Within the patient safety category, the strategy focuses on: procedures at a department or unit level for every risky process (including sanitation, equipment maintenance, medication administration etc); a reporting system for adverse events (see below); electronic patient records to promote increased safety in the exchange of information in and between hospitals and the private sector; and national standards which will become part of the system for quality assessment.

Within the communication of knowledge and transparency in the systems category, the focus is on: development of clinical guidelines; development of a quality assessment scheme; and development of quality declarations.

Within the competence development category, the strategy focuses on: quality improvement as an obligatory subject for all health professions; work-planning; enhanced cooperation between sectors; development of IT competencies; development and research; and development of common professional terminology.

Performance

The World Health Organization examined the relative performance of health systems of member countries.[10] 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 Denmark ranked 20th on the list (Canada 7, the U.K. 9, Australia 12, U.S. 15, and N.Z. 26).[11] The study also examined how efficiently health systems translate expenditure into health in regard to the overall achievement to expenditure. Denmark ranked 34th in the world (the U.K. 18, Canada 30, Australia 32, the U.S. 37 and New Zealand 41).[12] The responsiveness of health systems was also examined in regard to the level of responsiveness (defined as dignity, autonomy, and confidentiality, prompt attention, quality of basic amenities, access to social support networks during care, and choice of care provider). Denmark ranked 4th (the U.S. 1, Canada 7-8, Australia 12-13, New Zealand 22-23 and the U.K. ranked 26-27). In terms of distribution of responsiveness (disadvantaged groups), Denmark ranked 3-38 (i.e., it placed in the third tier, equal with 37 other countries, including the U.S., N.Z., Canada, the U.K. and Australia).

In terms of relative ranking within Europe, health status in Denmark has declined and thus it is no longer in the top rung of countries in Europe. Life expectancy increases have fallen relative to other countries in Europe, with high premature mortality due to too much smoking, a high fat intake, too little exercise and high alcohol consumption.[13]

Patient Safety

The Danes are a law-abiding society with acceptance of the need for social order, a strong social security network, and a broad tolerance for diversity. Their innovative approach to patient safety, which incorporates a separation of the pillars of patient compensation, professional discipline, and the reporting of adverse events, is seen as fundamental to the 'buy-in' of health professionals in Denmark. The importance of this factor in the view of all parties interviewed is worth underscoring.

Furthermore, it should be noted that patient safety is a 'hot button' issue throughout the Danish health care community. One example that was provided is the cover page of a June 2005 arthritis association magazine, with "Patientsikkerhed" (patient safety) as the headline and a picture of diaper pins as background.[14] This is illustrative of the high

[10] The World Health Organization, *The World Health Report 2000* (Geneva: The World Health Organization, 2004).
[11] Because of statistical uncertainty, Canada, the U.K. and Australia are in the same range with less than 0.5 percent difference between them.
[12] Again, Canada, Australia and Denmark are in the same range.
[13] Ministry of the Interior and Health, *supra* note 3 at 24.
[14] *Ledsager* 3:11 (June 2005).

level of focus on patient safety that is much more of a broad societal movement, not confined to the professional health care sector and to government representatives.

Key Statistics

A study of the adverse event rate in Danish public hospitals established that 9 percent of patients experience an adverse event while receiving treatment in hospital.[15] Forty-four percent were held to be preventable. Adverse events resulted, on average, in an additional seven days in hospital. As indicated in slides produced by the Danish Medical Association, "A general consensus, that something is rotten in the state of Denmark, was reached early."[16] A number of major initiatives that followed on the heels of this survey are discussed below.

Institutional Regulation

Standards

Institutional regulation is the responsibility of the National Board of Health. The Board may set standards. There are medical officers throughout the country who investigate and report to the Board on conditions in institutions. The Board can also instigate an investigation. However, it is limited in the kinds of actions it may take in that the counties exert substantial control at present regarding decision-making. Thus, the Board cannot insist that a particular institution be closed; its powers are limited to making recommendations, reporting to the Minister of Health, and potentially reporting to the public and the press.

The Copenhagen Hospital Corporation has voluntarily sought accreditation from the Joint Commission on Accreditation of Healthcare Organizations.

Funding and Accountability Mechanisms

In 1970, the Danish government delegated responsibility for funding and providing all public health care to the counties and local authorities. The counties and the municipalities of Copenhagen and Frederiksberg (through the Copenhagen Hospital Corporation) (15 in total) own and manage hospitals and pre-natal care centres and fund general practitioners, specialists, physiotherapists, dentists and pharmaceuticals through the National Health Security System. Local authorities are responsible for nursing homes, home nurses, health visitors, municipal dentists, school health services, and some public health responsibilities. Direction as to how health services should be organized and what services are provided is generally not specified in any great detail in legislation as it is a county/local authority responsibility. Counties and the Corporation have wide

[15] T. Schioler *et al.*, "Incidence of Adverse Events in Hospitals: A Retrospective Study of Medical Records" (2002) 164 Ugeskr Laeger 4377. Note that this study has been criticized for having too small a statistical base.
[16] J. Poulsen, "The Danish Patient Safety Act" (2005) [unpublished, archived with author].

powers to organize the system to meet local needs. However, the focus on controlling healthcare costs has resulted in a greater degree of formal cooperation. County council elections are held every four years and focus on local issues, so the managers of the health system are held directly accountable by voters. Legislation passed in 1994 requires counties, the Copenhagen Hospital Corporation and the municipalities to develop a health plan every four years to coordinate preventative and curative health care activity. These plans must be submitted to the National Board of Health for comment.

Monitoring Mechanisms

The Quality Assessment Programme originates from the economy agreements (funding agreements) between the national government and the county councils and the Copenhagen Hospital Corporation in 2002 and 2003, so currently it applies only to publicly-funded hospitals (although this is just phase one). It is a binding agreement to jointly establish and develop a comprehensive nation-wide system for assessing the quality of Danish health care services. It is governed by a steering committee with representatives from the regions/municipality, the National Health Board, and the Ministry of Interior and Health. This requires measuring and assessing quality indicators. There will be a common evaluation basis (standards, including indicators), common evaluation methods (self-assessment and external review) and common reporting (feedback, accreditation and publication). Standards were to have been set by Spring 2004. The primary means of assessment is continuous self-assessment supplemented by periodic review by Danish and Foreign experts. Accreditation of all publicly-funded hospitals will be completed by winter 2006. Results will be reported back to the individual health care institution. There will be periodic accreditation, publication, and benchmarking of assessments and indicators for comparable institutions. It is intended that this programme will cover all health care services in time.

Working Conditions Regulation

Most providers of health care services are salaried employees in public institutions or are self-employed people who work for the public on the contract basis, both as agreed to by collective agreements. Prior to August 2004, when the Working Time Directive came into force, junior doctors negotiated national collective agreements. While the maximum hours of work and maximum hours per shift were not regulated (but averaged 45 hours), the minimum hours between shifts were required to be between 8 and 11 hours. [17]

The European Working Time Directive was passed in 1993 by the European Commission.[18] Its aim is to improve workers' safety and protection. It limited working time to a maximum of 48 hours per week by November 1996. It included all of the medical profession except doctors in training, but allowed for individual opt-out. The

[17] Australian Medical Association, *Review of Overseas Experience in Regulating Hours of Work of Doctors in Training* (Kingston, ACT: Australian Medical Association, 1998).
[18] EC, *Council Directive 93/104/EC of 23 November 1993 concerning certain aspects of the organization of working time*, [1993] O.J.L. 307/18, online: Europa <http://europa.eu.int/comm/employment_social/labour_law/docs/directive93_104_en.pdf>.

European Court of Justice ruled in 2003 that hospital on-call hours are to be included in the calculation of hours per week.[19]

The European Working Time directive applies to junior doctors as of August 2004.[20] Junior doctors may work a maximum of 58 hours per week, to be reduced to 48 hours per week by 2009. There must be 11 hours' rest in every 24 hour period, a minimum 20 minute break when a shift exceeds six hours, and a minimum 24 hour rest every seven days or a minimum 48 hour rest every 14 days. Junior doctors required to work in excess of these limits may take their employers to employment tribunals, which may result in a fine.

Professional Regulation

Under the 1987 *Act on the Central Administration of the Health Services*[21], the National Board of Health, which is a subdivision of the Ministry of the Interior and Health, is responsible for individual and general supervision of physicians and nurses, including administration, planning and quality development of the training provided, certification, and licensing. Specific duties regarding supervision of health care personnel are included in the *Physicians' Act*, the *Act on Certification and Licensing of Health Care Professionals*, and the *Act on Medical Officers of Health*.[22]

The Danish Medical Association functions as a labour union for physicians and plays no role in professional regulation or discipline other than providing legal assistance for its members who are subjected to such proceedings.

Up until 1988 the National Board of Health was responsible for professional discipline. There was widespread concern that healthcare professionals were not being disciplined often or severely enough. Therefore the Patients' Complaints Board was established (see below under Patient Complaint Mechanisms for further discussion of this Board), becoming independent of the National Board of Health in 1994, and the National Board of Health was divested of a number of aspects of professional discipline. They do, however, retain various functions to do with discipline, including the authority to issue

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[19] *Landeshauptstadt Kiel v. Norbert Jaeger*, online: <http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=62002J0151>; *Sindicato de Médicos de Asistencia Pública (Simap) v. Conselleria de Sanidad y Consumo de la Generalidad Valenciana*, online: <Europehttp://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexplus!prod!CELEXnumdoc&lg=en&numdoc=61998J0303>.

[20] EC, *Council Directive 2000/34 of the European Parliament and of the Council of 22 June 2000 amending Council Directive 93/104/EC concerning certain aspects of the organization of working time to cover sectors and activities excluded from that Directive*, [2000] O.J.L.195/41, online: Europa <http://europa.eu.int/comm/employment_social/labour_law/docs/directive2000_34_en.pdf>.

[21] See Retsinformation, *supra* note 9.

[22] See *ibid.*

guidelines setting a standard defining, for example, what conduct would constitute misconduct.

The Patients' Complaints Board may choose to consult with representatives of the National Board of Health in rendering its decision. Also, the Patients' Complaints Board is not vested with authority to mete out discipline. Rather, a copy of the decision goes to the National Board of Health,[23] which chooses, based on the findings of the Patients' Complaints Board, whether or not to take action against the health care professional. In the first instance, the National Board of Health may advise the professional to improve her/his standards, and that the Board will take further action if another complaint is received. On the other hand, if the Board believes that the person's actions are grievously wrong, it may send the matter to the prosecution service, who will decide whether a criminal or malpractice action by the state should proceed to court. It also may order the revocation of a certificate or license to practice where the professional is believed to pose a threat to other people.

The experience over the last number of years with this severance of responsibilities has been dramatic, and not necessarily in the direction anticipated upon formation. The number of cases wherein discipline is viewed as warranted has gone from approximately 300/year to 50/year. Thus, it is clear that only the most egregious cases proceed to the National Board of Health for assignation of a penalty.

The various health care professional bodies have been supportive of the creation of the Patients' Complaints Board (discipline), the Patient Insurance Association (compensation), and the adverse events reporting system, in large measure because information is not to be shared between these three systems. The Patient Insurance Association decisions are shared with the National Board of Health, but not until information identifying the health care professional(s) is removed.

Products Regulation

The European Union has legislation governing medicinal products and devices. Member states must use this as the base for their legislation and may choose to supplement with their own requirements.

The Danish Medicines Agency is an independent agency of the Ministry for the Interior and Health. It is empowered under Danish law[24] to implement and enforce the legislation relating to medical devices, medicinal products, reimbursement on medicinal products,

[23] A copy also goes to the employer of the health care professional.

[24] See, Danish Medicines Agency, online: <http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=7696>, where it is stated that on 6 December 2005, the Danish Parliament passed the *Medicines Act* (DK), 2005/1180, online (in Danish online): www.retsinfo.dk. The Act was affirmed by the Queen on 12 December 2005 and entered into force on 17 December 2005.

pharmacies, and euphoriant substances. Its main objective is to ensure that medicinal products and devices used in Denmark are of satisfactory quality, are safe to use, and have the desired effect.[25]

Pharmacovigilance has received recent major focus with the creation of a pharmacovigilance consumer safety division in May 2005. It is mandatory for both physicians and the pharmaceutical industry to report adverse drug reactions to the Danish Medicines Agency. Patients or their families also have the option of reporting. In addition, physicians are to report serious incidents associated with the use of medical devices. There is legislation which creates a no-fault insurance scheme in respect of adverse events caused by pharmaceuticals and vaccines (see Compensation System below).

When a report of an adverse event is received by the Danish Medicines Agency, it is entered into a database of adverse drug reactions. This information is sent to the company that manufactures the product, to the European Agency for the Evaluation of Medical Products, and to the World Health Organization. Collected reports are analyzed for each product on a regular basis. As a result, the summary of the product characteristics and the product leaflet may be changed, the company may be required to carry out an extraordinary investigation, batches may be withdrawn, and, in rare cases, the product may be withdrawn from the market.[26]

If a clinical trial is to be carried out, approval must be sought from both the Danish Medicines Agency and the Scientific Ethical Committee. The Danish Medicines Agency evaluates the quality of the investigation and the safety of the patient, and the Scientific Ethical Committee investigates the ethical aspects.

As of July 2003, a Council for Adverse Drug Reactions was created. The Council is mandated to follow and assess the reporting of adverse drug reactions in practice and to provide recommendations to the Danish Medicines Agency for educational and communications initiatives. This initiative is intended to increase the quality of supervision of adverse drug reactions. The Council is also to act as a forum for dialogue between medico-professionals and people from other parts of society in order to encourage prevention and therefore safety.

Inquiry Processes

Denmark does not have a system of coronial or public inquiries. Suspicious deaths are first reviewed by the local Medical Officer, who reports any indication of criminal behaviour to the police for further investigation and possible prosecution.

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[25] Danish Medicines Agency, "The Danish Medicines Agency in 2003," online: Danish Medicines Agency <http://www.dkma.dk/1024/visUKLSArtikelBred.asp?artikelID=744>.

[26] Legislation not translated. See Danish Medicines Agency, "Reporting Adverse Reactions in Humans," online: <http://www.dkma.dk/1024/visUKLSArtikel.asp?artikelID=1519#what>.

Compensation Systems

The current patient insurance system was introduced in 1992. Prior to 1992, compensation was through the tort system based on the '*culpa*' principle. Two of the objects of the *culpa* principle are redress and prevention. Redress was considered not often achieved because an entitlement to damages was difficult to establish. Therefore, in most cases, patients did not try to obtain compensation and, if they did, faced a long and costly wait. Before 1992, it is estimated that at most only 250 patient injuries were reported to hospital authorities or insurance companies each year. In contrast, under the patient insurance system, in 2001, 2,800 injuries were reported to patient insurance[27] and in 1999, approximately DKK126,000,000 in damages were paid out.[28] The main reason for the introduction of the patient insurance scheme was to improve the legal recourse available to patients. The second reason was prevention. Under Danish law, an individual health professional did not pay damages unless he or she was grossly negligent or malicious. Instead, if mere negligence was established, employers of health care professionals paid the assessed damages. Employers, however, were covered through insurance. Therefore, little deterrent effect was felt by institutions and the local authorities that ran them and by the individual health providers.[29]

Physicians agreed that the tort system was problematic in its application to medical injury. They did not find it reasonable that a patient's ability to receive compensation depended upon the injured patient establishing that a mistake had been made by someone or by the institution. Physicians were placed in a conflict of interest with patients, since agreement that a mistake had been made could result in a complaint being made to the patient complaint board, and possible sanctions under professional regulations. Physicians wanted compensation to be established based on objective criteria, with no requirement that an injury be linked to negligence. They also sought separation of the compensation system from that of complaints in order to allow physicians to support patients in their efforts to receive compensation.[30]

The Patient Insurance scheme was introduced in 1992. It is considered to be 'no-fault' in that the patient claimant need not establish culpability or fault. The Insurance program does not report claims to the Patient Complaints Board, and vice-versa, as the program was deliberately structured to keep a separation between complaints and compensation. All hospitals employ patient counselors whose duty is to assist and advise patients on their rights and on the possibility of obtaining damages. Furthermore, there is a duty on healthcare professionals to advise patients of the possibility of compensation in case of a

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[27] Arne Grünfeld, "The Nordic Patient Insurance Systems: Similarities and Differences," online: Patientforsikringen <http://www.patientforsikringen.dk/uk/article/Nordic.html> [Grünfeld].
[28] The Patient Insurance Association, "The Danish Patient Insurance System," online: Patientforsikringen <http://uk.patientforsikringen.dk/public/dokumenter/pdf/aarsberetninger/engelsk/2000.pdf> ($1 CDN is approximately 5 DKK).
[29] *Ibid.*
[30] Grünfeld, *supra* note 27.

complication that could reasonably lead to such compensation being received. In 2002, 47.2 percent of claims filed were accepted by the Patient Insurance Association.[31]

The *Patient Insurance Act* is the most recent legislation governing this system.[32] Its object is to compensate patients/families for injuries sustained as a result of receiving a health care service. The scheme initially covered:

- Patients who sustain physical injury in connection with examination, treatment etc at a public hospital or a hospital which has an agreement with the state;
- Patients who sustain injury in connection with their participation in biomedical trials;
- Donors of tissue fluid, tissue and organs;
- Patients who receive free treatment or have a treatment grant for care in Denmark or outside of it.

The Act does not cover vaccination injuries.

Since 1 January 2004, the scheme covers all patients in public or private hospitals, patients treated at an accident site or in ambulances, and anyone being treated by an authorized health professional – including general practitioners, emergency physicians, specialists, dentists, dental hygienists and clinical dental technicians, chiropractors, physiotherapists, occupational therapists, psychologists, chiropodists, nurses, midwives, clinical dieticians, bioanalysts, prosthetists, orthotists, radiographers, and authorized health professionals in local authority healthcare services.

Either the hospital or the patient may commence a claim by completing and submitting a form. If the patient submits a form, the hospital must then also submit a completed form along with a copy of the patient's records. The patient may also be required to undergo an examination by a GP or specialist.

The reports and results of examination are reviewed by staff of the Patient Insurance Association. Most employees are legally trained, and healthcare professional specialists are retained part-time to provide medical opinions on claims. An oral hearing is not held unless requested by the injured patient. The written decision does not include the name or other identifying information as to the healthcare professional who rendered care.

Damages are paid if, in all probability, the injury was caused by either a preventable or an unavoidable injury. The level of probability required is that the likelihood be over 50 percent. Further, the Danish Supreme Court has stated that if the specialist standard (outlined below) was set aside, it is to be *presumed* that the injury was caused by the

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[31] Martin Ericsson, "Accident Compensation Corporation Videoconference" (Lecture presented to the New Zealand Accident Compensation Corporation, July 2003), online: Accident Compensation Corporation <http://www.acc.co.nz/wcm001/idcplg?IdcService=SS_GET_PAGE&nodeId=4249&ssUserText=ericsson >.

[32] No. 228 of 24 March 1997, as am. by No. 395 of 2 June 1999, is the most recent legislation governing this system.

failure to follow the standard.[33] A preventable or unavoidable injury is one of the following:

Preventable injury

- The usual specialist standard was not followed (This does not require the health professional to have acted negligently. Rather, the actions of the health care provider are compared to how an experienced specialist would have acted and the individual's own experience and knowledge is of no consequence. This applies both to diagnosis and to treatment. Note that with the addition of general practitioners in private practice in 2004, the applicable standard in their case is that of the best general practitioner);
- Defects in, or failure of, technical apparatus, instruments or other equipment (in its broadest sense);
- The injury would have been avoided had another treatment technique or mode of treatment been used, provided that that technique would have been equally effective at treating the illness (this does not apply to misdiagnosis); or
- Accidents (random, sudden, outside influence on the person which is independent of his/her will and results in provable bodily injury) which occur on hospital premises for which the hospital authority would be liable in tort (for example, slips on waxed floors, lift injuries, and fires).

Unavoidable injury

- An examination, treatment, injury in the form of infection or other complications that is more serious than what the patient could reasonably be expected to endure. The injury must be both reasonably serious and rare (i.e., occurs in less than 2% of cases) before compensation is granted. The courts and the Patients' Injury Board of Appeal have generously interpreted the 'reasonably serious' rule and, as a result, almost half of all claims are processed under this rule.[34]

Damages are not paid for injuries caused by pharmaceuticals, which are covered by a separate scheme (see below). Damages may be reduced or cancelled if the patient intentionally contributed to the injury or was grossly negligent. Damages will only be paid if they total a minimum of DKK 10,000,[35] or for dentists in private practice DKK 1,000,[36] and are calculated in accordance with the *Tort Liability Act*.[37] There is no mandated maximum. Loss of chance is non-compensable.

The Patient Insurance Association is funded by the county councils as self-insurers (previously there was a mix of privately purchased and self-insurance, but the insurance companies pulled out). The Association hears, reports upon, and settles all cases for damages.

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[33] *Ibid.*
[34] *Ibid.*
[35] Cdn $2,000.
[36] Cdn $200.
[37] Retsinformation, *supra* note 9.

A patient not satisfied with a decision of the Patient Insurance Association may appeal to the Patients' Injury Board of Appeal. The Board of Appeal is chaired by a judge. Members of the Board are appointed by a wide range of public bodies and include specialists depending on the nature of the claim, and legal, healthcare organization, and consumer appointees. Costs of administering the Board are paid for by the self-insured authorities. Approximately 20% of all Association decisions are overturned by the Board of Appeal.

Only following a decision of the Patient Insurance Association and the Patients' Injury Board of Appeal can an appeal be brought to the Danish High Court (the second level of court), which has the authority to uphold, annul, or change a decision. There is the possibility of appeal from the High Court decision to the Supreme Court, which is the court of final appeal in Denmark.

The system cost Danish taxpayers in 2004 approximately 45 million British pounds (34 million pounds in payment, plus interest, approximately 20%, plus administrative costs). The average amount of compensation was about 100,000 British pounds.

Compensation for adverse events caused by pharmaceuticals and by vaccines is covered by separate legislation. The *Danish Act on Damages for Pharmaceutical Injuries*[38] sets up a compensation scheme for those who are injured by medications or vaccines. Its object is to compensate patients or families for physical injuries caused by pharmaceuticals used in conjunction with medical treatment or research, or in the process of donation. It applies to pharmaceuticals dispensed through a pharmacy, hospital physician or dentist for consumption or clinical tests (it does not include naturopathic, homeopathic, vitamin and mineral preparations, unless they are used in clinical trials or vaccinations.) Damages are only paid for adverse event reactions where the reaction exceeds that which the injured person should reasonably accept. The state is responsible for paying the damages and expenses resulting from the scheme. The Minister of Health or delegate may calculate and dispense damages. State damages are subrogated to the patient's claim against pharmaceutical producers and middleman, as per the Danish *Product Liability Act.*[39] The state may choose to pay legal expenses for recovery of damages from the producer and amounts of damages recovered will accrue to the state.

The Pharmaceutical Injury Complaints Board hears appeals from the Minister's decision. It is chaired by a judge appointed by the Minister. Members are appointed by the Minister of Health, National Board of Health, Danish Pharmaceutical Society, the county council and metropolitan authorities, the federation of organizations for the disabled, and the Danish Consumer Council.

On a final note, the Patient Insurance Association has assembled perhaps the largest database in the world tracking specific cause of injury or missed diagnosis and patient

[38] No. 1120 of 20 December 1995, as am. by No. 1228 of 27 December 1996.
[39] No. 371 of 7 June 1989, as am. by No. 1041 of 28 November 2000.

prognosis. This is a major research tool for Danish researchers. The department, hospital, and region are identified in the data, but the name of the patient is not.

Other Patient Complaint Mechanisms

A patient concerned about the treatment he or she has received may launch a complaint with the Patients' Complaints Board. This Board is independent of the National Board of Health and is directed and staffed by lawyers. The basics of the Patients' Complaints Board were discussed *supra* under Professional Regulation, as the Board is integral to the system of discipline of health care professionals. This Board was established in 1988.[40] At that time it did not have the authority to make findings of fault. In 1994, the Board was granted independent agency status and was vested with the power to make such findings. It hears approximately one thousand cases per year. Interestingly, 85% are in relation to physicians,[41] despite the fact that Denmark has approximately 18,000 physicians and 80,000 nurses.

The mandate of the Patients' Complaints Board is to make findings of fact as to whether or not the health care professional has fallen below the standard expected in the circumstances. There are four different levels of adverse findings that can be made:

1. The treatment was not as good as it should have been.
2. The professional has not acted in accordance with good clinical practice.
3. The professional has not acted in accordance with good clinical practice and is advised to concentrate more in future.
4. The Board suspects that malpractice may be present and the police should investigate and decide whether to prosecute.

Each panel of the Board consists of a judge (as chair), two professionals from the relevant discipline, and two non-professionals appointed by a patient advocacy organization. The Board receives a report from a professional who has reviewed the facts prior to the Board convening. They may also consult with representatives of the National Board of Health.

Proceedings of the Patients' Complaints Board are not open to the public. In some cases a decision is posted on their website, but names are not published. This non-publication policy is the subject of controversy from time to time, and may change in the near future.

Adverse Event Reporting Systems

[40] Ministry of the Interior and Health, *supra* note 3 at 43.
[41] Medizinfo, "Introduction: Basic Principles of the Health Care," online: Medizinfo <http://www.medizinfo.de/jobborse/ausland/html/dk.html>.

Denmark was the first country in the world to set up a national adverse events monitoring system. Prior to this system being developed, a survey undertaken by the Danish Medical Association found that 1/3 of physicians from time to time considered changing their profession because of fear of being involved in adverse events; that the system in place did not motivate learning from adverse events; and that there was a definite willingness to report adverse events if confidentiality could be protected.[42] The Danish Medical Association decided that the focus to date had been on the wrong issue – i.e., blame placed on errant professionals – and that the focus should shift to learning from mistakes and near-misses.

The *Act on Patient Safety in the Danish Health Care System*[43] was passed in 2003 and came into operation on 1 January 2004. Its object is to improve patient safety; within Denmark it is referred to as a 'learning system', reflecting the fact that its major focus is to facilitate learning from adverse events and near-misses. The statute includes in its scope both private and public hospitals (in addition there is power for the Minister of Interior and Health to make rules that render the Act applicable to the primary care sector and to health care professionals in private practice). The Act requires mandatory reporting by health care professionals to hospital risk managers, who in turn must report to county councils (which administer the regional system). The risk managers and councils are to use this information in order to improve patient safety. Prior to the mandatory submission of this information to the National Board of Health, the information is stripped of identifiers, including ward number and name of the patient and health care professional(s).

The National Board of Health has established a national register to track events, and is to advise the health care system of identified safety risks. It also must produce an annual report on adverse events. An adverse event is defined as follows: "An adverse event shall mean an event resulting from treatment (defined as examination, diagnosis, clinical treatment, rehabilitation, specialist health care and prophylactic health care measures in relation to the individual patient) by or stay in a hospital and not from the illness of the patient, if such event is at the same time either harmful, or could have been harmful had it not been avoided beforehand, or if the event did not occur for other reasons. Adverse events shall comprise events and errors known and unknown."[44] Information may be shared without the consent of the patient or health care professional within the county council and the National Board of Health, and may be passed on to clinical databases and registers where information is kept for quality development in the health care sector.

Importantly, health care professionals may report anonymously if they so choose. Further, an individual who reports an adverse event cannot according to law be subject to disciplinary investigations or measures of any kind, including criminal sanctions, as a result of his/her report. Thus, there is a clear demarcation between on the one hand information gathered for purposes of complaints, investigations, and compensation, and information gathered under the national adverse events monitoring system. This element

[42] J. Poulsen, *supra* note 16.
[43] No. 429 of 10 June 2003.
[44] *Ibid.* at s. 2(1).

is seen as critical to gaining the initial and ongoing support of the health care professionals themselves, and does not appear to have resulted in discontent within the Danish public.

One of the measures of success of the system is to monitor whether or not it results in change on the hospital wards. In 2004, 6,000 reports were made, resulting in 137 specific proposals for change. These are often the result of 'root cause analysis' reviews. As it is estimated that 50% of adverse events are medication errors, it is not surprising that a frequent result of such reviews is a change by the risk manager in how medications are distributed.

Another measure of success is economic. In Denmark, serious adverse events (defined as events that cause harm and result in a prolonged stay in hospital or the provision of additional medical treatment) add an average of 7 hospital days per patient. It is believed that the cost of a national reporting system that reduces the incidence of adverse events is more than offset by the resulting savings in hospital expenditures.

The *Patient Safety Act* is to be reviewed in 2006. One of the issues is anticipated to be whether or not patients should also be entitled to report adverse events. Also, the Danish Patient Safety Society will argue that the primary care sector should be included as well as the hospital sector.

Other Legislative Instruments

There are at least two other pieces of law relating to the health system. The *Patients' Rights Law*[45] aims to contribute to ensuring that the patient's dignity, integrity and autonomy are respected and to ensure the relationship between patient and health care provider is one of confidence and confidentiality. It covers all patients who receive services within the public or private sectors from a health care provider (professionals authorized by legislation and those under their supervision). It addresses informed consent, hunger strikes, blood transfusions, end-of-life issues, living wills, access to health information, and confidentiality.

The second is *Order No. 665 of 14 September 1998 on information and consent and the communication of information relating to health, etc.*[46] It contains provisions relating to informed consent, and the right not to know.

[45] No. 482 of 1 July 1998.
[46] *Lovtidende, 1998* Part A, 22 September 1998, No. 133 at 3877-3880.

Patient Safety Law:
From Silos to Systems

Appendix 2: Country Reports
NEW ZEALAND

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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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New Zealand

New Zealand is a constitutional monarchy with a unitary system of government. The population of New Zealand is 4,056,000.

Health Care System Context

Law

New Zealand has a common law system.

Health

The foundations of the New Zealand health system are: a public system funded predominantly through taxes; a universal system of free health care; a stewardship role for the state; partial de-centralization; concerns about efficiency and meeting *Treaty of Waitangi* commitments to Māori in relation to health and welfare.

Health Services Delivery

In 1999, 77.5 percent of health care services were funded through taxation, although health services may often be delivered through private health care providers, such as private hospitals, and specialists. Co-payments are usually charged for general practitioners and pharmaceuticals.

New Zealand has been a country where marked ideological swings have shaped the health sector since 1984 in a variety of ways. There have been no less than four major restructurings of the manner in which health policy, purchasing and funding decisions are made and publicly funded or provided health care services are delivered.[1] The latest wave of reforms in terms of the structure of health service policy and delivery in New Zealand occurred in 2000 with the *New Zealand Public Health and Disability Act 2000*. The Act sets out the respective roles and responsibilities of the Minister of Health and the District Health Boards in regards to the operating of the health system.

[1] Robin Gauld, "One Country, Four Systems: Comparing Changing Health Policies in New Zealand" (2003) 24:2 International Political Science Review 199.

The Ministry of Health is now the chief provider of policy advice to government in respect of the health sector and is responsible for health sector direction. Some planning and purchasing functions remain with the Ministry of Health. For example, the Ministry of Health may enter into 'Crown Funding Agreements' to provide health services. These include global budgets negotiated with District Health Boards. However, many planning and purchasing functions have been devolved to the newly created District Health Boards. The Minister is required to develop a national health and national disability strategy to provide the framework for the government's overall direction of the health sector.[2] These strategies highlight priorities for District Health Boards and other service providers and detail goals and targets that must be met. The Minister of Health is also required to develop a quality improvement strategy for the health sector.[3] The Minister must report annually to the House of Representatives on progress in implementing these strategies. The Minister may issue directions to District Health Boards which must be complied with. It may also place Crown monitors on the boards of District Health Boards to assist in improving performance if the Minister thinks it is desirable.

There are 21 District Health Boards created on a regional basis, funded by the Ministry of Health. District Health Boards are responsible for planning, providing and purchasing services (primary, secondary and tertiary, personal and population based) in consultation with the community. They provide health services through the public hospitals in that District which are part of the Board. The objectives of the District Health Boards are to:

- improve, promote, and promote the health of people and communities;
- promote the integration of health services;
- promote effective care or support for those in need of personal health services or disability health services;
- promote inclusion and participation in society and independence of people with disabilities;
- reduce health disparities by improving health outcomes for Māori and other population groups;
- reduce, with a view to eliminating, health outcome disparities between population groups within New Zealand by developing and implementing (in consultation) services and programmes designed to raise health outcomes;
- exhibit a sense of social responsibility by having regard to the interests of the people for whom it provides or arranges services;
- foster community participation in health improvement and in planning for the provision of and changes to services;
- uphold ethical and quality standards commonly expected of providers of services and public sector agencies;
- exhibit a sense of environmental responsibility by having regard to environmental implications for its operations;
- be a good employer.[4]

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[2] *New Zealand Public Health and Disability Act 2000* (N.Z.), 2000/91 at s. 8 [*Public Health and Disability Act*].
[3] *Ibid*. at s. 9.
[4] *Ibid*. at s. 22.

District Health Authorities have a number of functions, including to:

- ensure the provision of services to its resident population and for other persons as specified in the Crown funding agreement;
- actively investigate, facilitate, sponsor, and develop cooperative and collaborative arrangements with persons in the health and disability sector to improve, promote, and protect the health of people and promote the inclusion and participation in society and independence of people with disabilities;
- issue relevant information to the population;
- establish and maintain processes for Māori to participate in, and contribute to, strategies for Māori health improvement;
- continue to foster the development of Māori capacity to participate in the health and disability sector and to provide for the needs of Maori;
- provide relevant information to Māori;
- regularly investigate, assess, and monitor the health status of its resident populations, any factors that many be adversely affecting health, and the needs of the population for services;
- promote the reduction of adverse social and environmental effects on the health of people and communities;
- monitor the delivery and performance of services by it and by persons engaged by it to provide for, or arrange, the delivery of services;
- participate, where appropriate, in the training of health professions;
- provide information to the Minister for the purposes of policy development, planning and monitoring in relation to the performance of the District Health Board and to the health and disability support needs of New Zealanders.[5]

The Boards of District Health Authorities are accountable to the Minister. Each Board must determine a District Strategic Plan and review it on a three year basis. It must not be inconsistent with the Health or Disability strategy and full consultation must occur. It also must create an annual plan which must be agreed upon with the Minister.

The District Health Boards have five shared service bureaus to create economies of scale in information management, financial planning and contract negotiation. Five members of the Board of each District Health Authority are appointed by the government, and seven are directly elected by the public – two members must be Māori who if not elected must be appointed. The Boards are also required by law to have three statutory advisory committees: community and public health; disability support; and hospital. Members of these committees are appointed by the Board.

Primary health care is provided by a variety of providers in the community including doctors, nurses and midwives. Many are paid on a fee for service basis, although more are moving to a capitated model. The recent reforms encourage the development of Primary Health Organisations (PHOs), which are modeled on the successful developments in primary care in England. However, under the New Zealand model

[5] *Ibid*. at s. 23.

PHOs negotiate a global budget with the District Health Authorities for the provision of services to a defined population. The PHOs in New Zealand do not in turn budget-hold for the purchase of secondary or tertiary facilities. PHOs are not-for-profit and must work with their community to achieve the goals set out in the government's Primary Health Care Strategy. PHOs are accountable to the District Health Board.

PHARMAC

PHARMAC is New Zealand's national pharmaceutical purchasing agency for drugs. It has been in existence since 1993 but became a stand alone agency after the reforms of 2000. PHARMAC promotes the responsible use of pharmaceuticals, which includes communicating with health professionals to encourage optimal prescribing and health outcomes for patients and running patient information campaigns. In September 2001, PHARMAC was authorized by the Minister of Health, under section 48(e) of the *New Zealand Public Health and Disability Act 2000*, to manage the purchasing of hospital pharmaceuticals on behalf of District Health Boards pursuant to the National Hospital Pharmaceutical Strategy which was approved by the Minister of Health in February 2002. PHARMAC also subsidizes selected drugs at a national level through a listing process that aims to enable New Zealanders to access effective drugs through government subsidization within a limited budget.

Advisory Bodies

The National Advisory Committee on Core Health and Disability Services was established in 1992 (formerly the National Advisory Committee of Health and Disability). In 1996 the Committee's brief was extended to include public health services and it became known as the National Advisory Committee on Health and Disability (the National Health Committee). Since 2000 the Committee's status is established by statute.[6] Its brief is to advise the Minister of Health about: the types of health and disability services that should be publicly funded; matters relating to public health; and any other matters at the request of the Minister.[7] In 2000, the Minister asked the Committee to examine issues relating to health care quality.

In May 2002 the National Health Committee released a report entitled *Safe Systems Supporting Safe Care: Final Report on Health Care Quality Improvement in New Zealand*.[8] The report defines quality as involving five interrelated concepts: safety; consumer focus; access; effectiveness; and efficiency. It recommends that quality improvement should be the prime focus of health care delivery in New Zealand, focusing in turn on improving processes and interactions between people at all levels of the health care system. Quality is seen as a responsibility of all individuals and teams in the health care sector as well as organizations and governments. The framework is based on the

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[6] *Ibid*. at s. 11.
[7] National Health Committee, online: NHC <http://www.nhc.govt.nz/>.
[8] National Health Committee, *Safe Systems Supporting Safe Care: Final Report on Health Care Quality Improvement in New Zealand* (Wellington: National Health Committee, 2002).

Treaty principles of partnership and participation, and the idea of cultural competency, the ability to integrate different cultural perspectives and respond appropriately to the cultural needs of individuals. It identified four priorities for action: stronger leadership; improved responsiveness to Māori; greater consumer involvement and better coordination. Leadership should be at the individual, team, organization and overall system level. It considers that government has a leadership role in creating the right environment through strategic direction, commitment and resourcing for a culture of improvement to flourish. It suggests that the Ministry should be the leader for quality improvement in health care and be accountable for it. It suggests a quality improvement network, regular forums on quality improvement, a 'health innovations' fund to fund quality improvement strategies and an awards scheme to recognize achievements in quality improvement. It also recommends consumer and Māori participation in accreditation, audit, policy development and through consumer satisfaction surveys.

In 2003 the Minister of Health published *Improving Quality (IQ): A Systems Approach for the New Zealand Health and Disability Sector*[9] as her response to the requirements of the *New Zealand Public Health and Disability Act 2000* and to the National Health Committee's report. The paper supports a systems approach to quality. The dimensions of quality are identified as being: people-centred, access and equity, safety, effectiveness, efficiency resting on the foundations of partnership, participation and protection set out in the *Treaty of Waitangi*. Eleven goals are identified:

- more effective service outcomes for Māori;
- leadership which supports constant maintenance and improvement in service quality and takes into account Māori aspirations and priorities;
- public participation in planning, delivery and assessment of health and disability services and programs, including Māori;
- awareness, understanding and commitment to a quality improvement culture at all levels;
- evolutionary redesign of systems of care to support delivery of quality services;
- adverse outcomes managed in an open and supportive manner that builds trust and confidence in the system and is fair to all participants;
- there is effective and open communication, co-ordination and integration of services;
- a supportive and motivating environment that provides the workforce with appropriate tools for learning and improvement in planning, delivery and assessment;
- useful knowledge and information is readily shared;
- regulatory protections that assure safe care in place to support people and service providers;
- regular review of these goals.

[9] N.Z., Minister of Health, *Improving Quality (IQ): A Systems Approach for the New Zealand Health and Disability Sector* (Wellington: Ministry of Health, 2003), online: Ministry of Health < http://www.moh.govt.nz/moh.nsf/ea6005dc347e7bd44c2566a40079ae6f/f9eb9f14e7626b8ccc256d96007f6b4e?OpenDocument> [*Improving Quality*].

The strategy to achieve these goals is to:

- reinforce key nationwide standards and quality assurance programs ;
- focus on standards and quality assurance expectations of District Health Boards;
- use advisory committees set up under the *New Zealand Public Health and Disability Act 2000* as a sector-wide quality assurance mechanism.

The government developed the *IQ Action Plan: Supporting the Quality Improvement Approach*, which identifies 55 actions to be undertaken in support of the eleven goals above. The action plan is to be updated at least once every three years by the Ministry of Health with input from the health sector.[10]

The Health Workforce Advisory Committee was established under the *New Zealand Public Health and Disability Act 2000*.[11] Its focus is on building appropriate workforce capacity and it looks at training, recruitment and retention issues.[12] The Committee has identified healthy workplace environments as one of its seven priority areas for health workforce development.[13] It is currently developing national Healthy Workplace Environments guidelines with the goal of improving recruitment and retention, workplace diversity, organizational performance, and the quality of work life for health practitioners. The guidelines are expected in late 2005.[14]

The National Health Epidemiology and Quality Assurance Advisory Committee is established under section 17 of the *New Zealand Public Health and Disability Act 2000*.[15] It may advise the Minister of any health epidemiology and quality assurance matter but must specifically deal with morbidity and mortality issues concerning the perinatal, infant or child and adolescent sectors. The Minister must present Parliament with copies of reports from this committee and mortality review committees.

Mortality Review Committees were also established pursuant to the Act.[16] Their mandate is to review deaths of persons or classes of persons with a view to reducing the numbers of deaths and to ensure continuous quality improvement through the promotion of quality assurance programmes. The Committees report to the Minister of Health and

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[10] N.Z., Minister of Health, *IQ Action Plan: Supporting the Quality Improvement Approach* (Wellington: Ministry of Health, 2003), online: Ministry of Health < http://www.moh.govt.nz/moh.nsf/49ba80c00757b8804c256673001d47d0/3792aa50e9ef5ff2cc256d9f0016b2ab?OpenDocument>.

[11] *Supra* note 2 at s. 15.

[12] Health Workforce Advisory Committee, online: HWAC < http://www.hwac.govt.nz/about/about.htm>.

[13] Health Workforce Advisory Committee, "The New Zealand Health Workforce – Future Directions – Recommendations to the Minister of Health 2003," online at: HWAC < http://www.hwac.govt.nz/publications/HWACfuturedirections03.pdf >.

[14] Health Workforce Advisory Committee, "Health Workforce Advisory Committee Fourth Annual Report to the Minister of Health" (December 2004), online: HWAC < http://www.hwac.govt.nz/publications/hwacannualreport2004.pdf>.

[15] *Supra* note 2.

[16] *Supra* note 2 at s. 18.

their members are appointed by the Minister. The Child and Youth Mortality Review Committee[17] was established by the Minister in 2001 and its purpose is to:

- monitor the number and types of deaths that occur in children and youth over time ;
- educate the public about the usefulness of and need for mortality review;
- encourage the establishment, effective functioning and nation-wide co-ordination of local mortality review committees;
- provide information to local mortality review committees that assist the review process and that encourages local responses to reduce the risk of death for children and youth;
- create links and interact with community and organizational networks, in particular those in Māori, Pacific and other communities with a high child and youth mortality;
- collect from all relevant sources information that will identify preventable factors or systems failures that could be improved both locally and nationally;
- conduct specific time limited investigations into particular types of child and youth deaths that will identify specific actions that can be taken at both local and national levels that will prevent child and youth deaths;
- produce an annual report to the Minister of Health outlining their results and making recommendations for actions that will reduce child and youth deaths;
- advocate for the improvement of health and social services for children and youth where these actions have a direct bearing on reducing child and youth deaths;
- sponsor, support and promote research that will identify new factors that will prevent child and youth deaths.

A second ministerial committee, the Perinatal and Maternal Mortality Review Committee, was established in 2005.

The New Zealand Guidelines Group was set up initially as an informal network by the National Health Committee. It is now an independent autonomous incorporated society that is funded by the Ministry of Health with some financial contributions from agencies such as ACC and the National Health Committee.[18] NZGG co-ordinates and provides technical advice to a number of Ministry of Health advisory groups. NZGG works with a broad-based collaborative network of clinical leaders, policy-makers, health administrators and consumers, designing tools to promote an evidence-based culture within the New Zealand health and disability sector. These tools include: evidence-based guidelines; the circulation of the latest evidence-based news from New Zealand and overseas; links to the international Cochrane Collaboration; and training.

Mental Health System

[17] Child and Youth Mortality Review Committee, online: CYMRC <http://www.newhealth.govt.nz/cymrc/about/establishment.htm>.
[18] See the New Zealand Guidelines Group, online: NZGG <http://www.nzgg.org.nz>.

The Mental Health Commission was established as a ministerial committee under Section 46 of the *Health and Disability Services Act 1993*, and began work in September 1996. The Commission was established in response to the recommendations of the 1996 Mason Inquiry into Mental Health Services. A key part of its role is to ensure the implementation of the national mental health strategy by monitoring and reporting on the performance of key agencies. Following the enactment of the *Mental Health Commission Act 1998*, the Mental Health Commission was established as a Crown entity beginning 1 April 1998. The Commission originally had a five year life and was to be disestablished in August 2001. Under the *NZ Public Health and Disability Act 2000* the life of the Commission was extended to 31 August 2004. This legislation also provides for a further extension of the Commission's term, by Order in Council, to a date no later than 31 August 2007.

The Commission's specific functions are defined by the *Mental Health Commission Act* 1998. There are three key functions:

- to monitor and report to Government on the performance of the Ministry of Health in the implementation of the National Mental Health Strategy;
- to work with the mental health sector to promote better understanding by the public of mental illness, and eliminate discrimination; and
- to strengthen the mental health workforce.

The Commission has a legislative mandate to monitor the performance of key sector agencies and facilitates and promotes:

- leadership at all levels within the mental health sector;
- use of evidence based practices in all aspects of mental health service delivery to lead to best possible outcomes for service users, particularly for Māori;
- innovation and continued service improvement and development.

The Commission has the flexibility to undertake whatever tasks are required to meet its responsibilities. This includes reviewing, examining and reporting back to the Minister on the status of the mental health system, the progress being made toward achieving the mental health strategy and finding out what barriers are preventing the objectives being reached.

The Treaty of Waitangi

The *Treaty of Waitangi* is a Treaty dating from 1840 between Māori iwi and hapū (tribes and sub-tribes) and the Crown. It is the founding document of New Zealand. The Treaty was intended by Great Britain to be an exchange of sovereignty in return for a guarantee of the authority of the chiefs and the protection of Māori land and resource rights. The Treaty also extended to Māori the same rights and privileges as British citizens had. Māori did not believe that when they signed the Treaty they were relinquishing their sovereignty. The different interpretations of the Treaty remain a contentious issue to this day. Successive recent governments (since the late 1970s) have recognised the importance of the Treaty. The Treaty of Waitangi has never been made a formal part of the New Zealand constitutional system but many statutes refer to it. In 1994, the Privy

Council commented that the Treaty "is of the greatest constitutional importance to New Zealand". New Zealand courts hold similar views and are actively interpreting statutes that mention the Treaty in a way that gives effect to the obligations of the Treaty. The government takes very seriously its obligations towards Māori and references to the Treaty are incorporated into most legislation and policy documents. In addition, more specific actions are taken by government to give effect to obligations under the Treaty. For example, in relation to health services, the government often requires consultation and enables Maori participation in health services management at all levels. It provides health services specifically to meet Māori needs, often managed by Māori, or requires general health services, and providers of health services (individual and institutional), to be conversant with, and sensitive to, the needs and beliefs of Māori.

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.[19] Each country studied had different areas of good performance and weakness. New Zealand had significant improvement in asthma mortality which the Fund called a 'true success' story and the relative survival rate for colorectal cancer was the highest. New Zealanders reported the fewest problems accessing care on nights and weekends, getting same day appointments, and waiting for emergency care. New Zealanders reported the least coordination of care problems, good patient-doctor communication and the highest overall physician responsiveness. In contrast, the suicide rate is higher than the other four countries, especially for the young. Stroke case fatalities were higher among older age groups. Influenza and polio vaccines were low and breast cancer screening rates were lowest.

The World Health Organization examined the relative performance of health systems of member countries.[20] 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 New Zealand ranked 26th on that list (the United Kingdom 9, Canada 7, Australia 12, U.S. 15, and Denmark 20).[21] The study also examined how efficiently health systems translate expenditure into health in regard to the overall achievement to expenditure. New Zealand ranked 41st in the world (the United Kingdom 18, Canada 30, Australia 32, Denmark 34, and the U.S. 37).[22] The responsiveness of health systems was also examined in regard to the level of responsiveness (defined as dignity, autonomy, and

[19] The Commonwealth Fund, *First Report and Recommendations of the Commonwealth Fund's International Working Group on Quality Indicators* (New York: The Commonwealth Fund, 2004), online: The Commonwealth Fund < http://www.cmwf.org/publications/publications_show.htm?doc_id=227628>.
[20] The World Health Organization, *The World Health Report 2000* (Geneva: The World Health Organization, 2004).
[21] Because of statistical uncertainty Canada, the U.K. and Australia are in the same range with less than 0.5 percent difference between them.
[22] Canada, Australia and Denmark are in the same range.

confidentiality, prompt attention, quality of basic amenities, access to social support networks during care and the choice of care provider). New Zealand ranked 22-23 in the world (U.K. ranked 26-27 (with Qatar), the U.S. 1, Denmark 4, Canada 7-8, Australia 12-13). In terms of distribution of responsiveness (disadvantaged groups), New Zealand ranked 3-38 (i.e. third equal with 37 other countries, including the U.S., the U.K., Canada, Denmark and Australia).

New Zealand had the lowest per capita health spending in 2000 ($1,623, compared with $1,763 in the United Kingdom, $2,211 in Australia, $2,535 in Canada, and $4,631 in the United States).[23]

Patient Safety

Key Statistics

Recent research suggests that the adverse event rate in New Zealand hospitals averages 12.9 percent with a death or permanent disability rate of 2 percent.[24]

Institutional Regulation

Traditionally, the regulation of institutions that provide health care in New Zealand has been accomplished through input regulation (e.g. ratios of toilets to residents). However, it is increasingly recognized that input regulation does not necessarily result in good results or outcomes.[25]

The *Health and Disability (Safety) Act 2001* applies to institutions that provide hospital, rest-home (long-term care), and residential disability services, as well as to other types of health and disability providers as specified by the Minister. The objectives of the Act are to:

- Promote safe health and disability services;
- Establish consistent and reasonable standards for health and disability services;
- Encourage health and disability services providers to take responsibility for safely providing services; and

[23] G.F. Anderson *et al.*, "It's the Prices, Stupid: Why the United States Is So Different from Other Countries" (2003) 22:3 Health Affairs 89.
[24] Peter Davis *et al.*, "Adverse Events in New Zealand Public Hospitals I: Occurrence and Impact" (2002) 115 N Z Med J 1167.
[25] *Improving Quality*, *supra* note 9 at 37.

- Encourage health and disability services providers to continuously improve service quality.[26]

Medical, surgical, pediatric, maternity, age-related, mental health, intellectual disability services and disability services are all covered by the Act.

Standards

From October 2004, all providers under the Act who must obtain certification must comply with the generic *Health and Disability Sector Standards NZS 8134:2001.* Others must comply with the Standards if cited in funder contracts. Where compliance is not a requirement, the Standards are intended for adoption more broadly across the sector on a voluntary basis, as it promotes current accepted good practice. The standards set minimum safety levels and encourage continuous quality improvement in six areas: consumer rights, service delivery, managing service delivery, organizational management, pre-entry and entry to services, and safe and appropriate environments.[27] It also sets out criteria through which compliance with the standards is assessed. Some criteria apply to all health and disability service providers, including sole practitioners, some only to services provided within facilities, i.e. day services or acute, short stay or overnight services, and some to long-stay and residential services only. A commentary assists with interpretation of the Standards and their criteria. So for example,

Standard 2.3 *All adverse, unplanned or untoward events are systematically recorded by the service. Appropriate statutory agencies are notified of essential information in an accurate and timely manner by the responsible service provider.*

Criteria 2.3.1 The service provider documents adverse, unplanned or untoward events including service shortfalls in order to identify opportunities to improve service delivery, and to identify and manage risk.

Comment.2.3.1 *This may be achieved by but is not limited to recording/reporting:*
(a) Accidents and incidents;
(b) Adverse clinical events;
(c) Complaints and Suggestions;
(d) Infections/notifiable diseases;
(e) Others as indicated by legislation, regulation or professional practice standards.

Certain providers (hospitals, rest homes and residential disability services) must also comply with the *Infection Control Standard NZS 8142:2000* and *Restraint Minimisation and Safe Practice Standard NZS 8141:2001* to receive certification under the Act. When these providers offer mental health services, they must also meet the *National Mental*

[26] *Ibid.* at 36.
[27] *Ibid.*

Health Sector Standards NZS 8143:2001. These standards relate to quality assurance and quality improvement activities.

Certification is the process by which organizations comply with the requirements of the *Health and Disability (Safety) Act 2001*. Each facility undergoes a certification audit by an independent auditor, who is designated by the Director-General of Health based on technical expertise and competence. Providers may receive certification for three years or for a lesser period if there are concerns. If the facility demonstrates safety and continual improvement, then certification may be for a maximum five year period. If the facility does not meet certification standards it cannot operate. The Ministry collects summary reports of the audits and records them in a database to facilitate analysis. The Ministry has an obligation to monitor and thus to analyze and react to the data gathered.

This is a new process and there is no information, as yet, as to how effective it is.

Accreditation is voluntary in New Zealand and there appear to be no financial incentives for a facility to be accredited.

Funding and Accountability Mechanisms

Crown Funding Agreements (CFA) reached between the Minister of Health and DHBs set out funding levels and performance expectations for DHBs.[28] Additional accountability documents that DHBs must comply with under the CFA include:

- *Indicators of DHB Performance:* a monitoring instrument that contains performance indicators;
- *Service Coverage Schedule:* a document that outlines the services that DHBs must ensure the population has access to;
- *Operational Policy Framework*: a document that states all the rules DHBs must comply with when funding or providing services. [29]

Quality and safety expectations are outlined in some of these documents.[30] The documents are annually updated.

Monitoring Mechanisms

The *New Zealand Public Health and Disability Act 2000* requires District Health Boards to monitor the performance of service providers that it contracts with.[31] The Ministry of

[28] N.Z., Ministry of Health, "A.I.M 3: Accountability Arrangements" (2002), online: MOH: <http://www.newhealth.govt.nz/aim/aim3/accountabilityarrangements.htm>.
[29] *Improving Quality*, *supra* note 9 at 40.
[30] *Ibid.*
[31] *Public Health and Disability Act*, *supra* note 2 at s. 23(1)(i).

Health is responsible for monitoring the performance of District Health Boards and does so on a quarterly basis.

Working Conditions Regulation

The *Health and Safety Employment Act 1992* is occupational health and safety legislation. The *Health and Safety Amendment Act 2002* defines hazard to include "[hazards] resulting from physical or mental fatigue …" This amendment is said to more clearly highlight that employers must consider the effects of physical and mental fatigue on their employees.[32]

Professional Regulation

The *Health Practitioners Competence Assurance Act 2003* provides a single legislative framework for the regulation of health practitioners in New Zealand. Fully in force since September 2004, the Act repeals eleven discipline-specific statutes that governed thirteen professions. [33]

The purpose of the Act is "to protect the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practice their professions."[34] The basic principles in the legislation are of "ongoing competence and the separation of the registration process from the disciplinary process."[35] The Act establishes independent registration authorities for each profession and a separate independent disciplinary tribunal for all health practitioners. It creates a consistent accountability regime for health practitioners and gives protections for approved quality assurance activities. The Act also introduces scopes of practice for all health practitioners.

Key protections in the Act include:

- registered health practitioners must not practice outside their scope of practice;

[32] N.Z., Department of Labour and Accident Compensation Corporation, *ACC Medical Misadventure and Its Wider Context: A Report Prepared for Review of Medical Misadventure Steering Group* (Wellington: Department of Labour and ACC, 2002) at 17.
[33] (N.Z.), 2003/48 [*Health Practitioners Competence Assurance Act 2003*].
[34] *Ibid.* at s. 3(1).
[35] N.Z., Ministry of Health, "Snapshot of the Act", online: MOH < http://www.moh.govt.nz/hpca#1>.

- registration authorities are required to ensure that a practitioner is competent to practice in his or her scope of practice upon registration and when they issue an annual practicing certificate;
- certain activities are restricted to registered health practitioners where necessary to protect the public from the risk of serious or permanent harm;
- it is illegal for individuals who are not registered under the Act to claim to be practicing a profession regulated by the Act or to use the titles protected by the Act. [36]

The Act is administered by the Ministry of Health. The Minister may appoint registration authority members, audit registration authorities and recommend restricted activities.[37] However, the primary responsibility and accountability for ensuring health practitioners are competent and safe to practice rests with the relevant registration authorities. Their tasks include the registration and recertification of health practitioners and the setting of standards for clinical competence, cultural competence and ethical conduct.[38]

Registration authorities must ensure that an applicant for registration has the appropriate qualifications and is competent and fit for registration.[39] Each practitioner must register within a scope of practice, which are defined by their registering authority.[40] In the case of medical practitioners, the Medical Council of New Zealand has created three broad scopes of practice: a general scope, a vocational scope for the 35 specialist branches of medicine recognized in New Zealand, and a special purpose scope for research, sponsored training and teaching activities.[41] When authorizing a practitioner's scope of practice, a registration authority can place conditions (such as prohibited tasks or supervision) on how he or she practices within that scope "to ensure the competent practice of the applicant."[42]

Before issuing a health practitioner an annual practicing certificate (APC), registration authorities must ensure that the practitioner meets "the required standard of competence".[43] The Act enables registration authorities to recognize or set competence programmes for health practitioners who hold or apply for APCs in order to ensure their ongoing competence.[44] The Medical Council of New Zealand evaluates a doctor's current competence for APC purposes based on his or her participation in continuing professional development programmes.[45] To maintain general registration, medical

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[36] *Supra* note 33 at ss. 7-9.
[37] *Ibid.* at ss. 9, 120, 124. See also s. 123-129 of the *Health Practitioners Competence Assurance Act 2003*.
[38] *Ibid.* at s. 118 (this section provides a complete list of a registration authority's functions).
[39] *Ibid.* at s. 15.
[40] *Ibid.* at ss. 17(2)(b)(i), 11Sections 17(2)(b)(i) and 11.
[41] Medical Council of New Zealand, "Registration Policies," online: Medical Council of New Zealand <http://www.mcnz.org.nz/Default.aspx?tabid=901>.
[42] *Health Practitioners Competence Assurance Act 2003*, *supra* note 33 at s. 22(3).
[43] *Ibid.* at s. 29(1).
[44] *Ibid.* at ss. 40, 118(e).
[45] Medical Council of New Zealand, "Continuing Professional Development and Recertification" (September 2004), at 3, online: Medical Council of New Zealand <http://www.mcnz.org.nz/portals/1/recertification.pdf>.

practitioners must participate in an oversight system where they work with a peer in a related vocational branch, who assists them in choosing and undertaking a minimum of 50 hours of continuing medical education, quality audit and peer review activities.[46] Doctors seeking continued vocational or specialist registration must participate in an approved branch advisory body recertification programme.[47] When applying for their APC, doctors must declare their continuing professional development activities as well as information regarding their fitness to practice.[48] Each year a percentage of applications are audited by the Medical Council.

If a registration authority becomes aware of concerns that a health practitioner is not competent to practice, the authority must make inquiries into these concerns and may review the competence of that practitioner.[49] If after a review the authority has reason to believe that the practitioner is not competent, it may order the practitioner to enter into a competence programme, set conditions for the practitioner's scope of practice, require the practitioner to sit an examination or undertake an assessment, or to receive counseling or assistance from nominated persons.[50] Should there exist reasonable grounds for believing the practitioner's lack of competence poses a serious risk of harm to the public either before or after a review or if a practitioner fails to satisfy the requirements of a required competence or recertification programme, the registration authority may suspend the practitioner's practicing certificate or alter his or her scope of practice.[51] Competence reviews done by the Medical Council are not made public, unless they result in restrictions or suspension of a doctor's practice.[52] When the registration authority becomes aware of a physical or mental condition that may prevent a practitioner from effectively functioning in his or her profession, it can order a medical examination, suspension and impose conditions on practice.[53]

A mandatory reporting scheme was mooted in respect of competence issues related to health professionals in the initial draft *Health Practitioners Competency Assurance Bill* i.e. mandatory reporting by a practitioner if that practitioner has reason to suspect that another practitioner is not competent or is sexually abusing patients. However, the clause was removed after intense public debate and opposition, primarily lead by the medical profession. In the current legislation, health practitioners who have reason to believe that another health practitioner may pose a risk of harm to the public by practicing below the required standard of competence may advise their regulatory authority of their concerns in writing and be protected from civil or disciplinary proceedings, providing that

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[46] *Ibid.* at 10-11.
[47] *Ibid.* at 8.
[48] Dr. Phillip Barham & Sue Ineson, "Maintaining Licensure – Ensuring Doctors Are Competent and Fit to Practice" online: Medical Council of New Zealand <http://www.mcnz.org.nz/portals/1/competence/pepposter.pdf>.
[49] *Health Practitioners Competence Assurance Act 2003*, *supra* note 33 at s. 36(1).
[50] *Ibid.* at s. 38.
[51] *Ibid.* at ss. 39(2)(a), 43(1)(b).
[52] Medical Council of New Zealand, "Performance Assessment ," online: Medical Council of New Zealand < http://www.mcnz.org.nz/Default.aspx?tabid=1084>.
[53] *Health Practitioners Competence Assurance Act 2003*, *supra* note 33 at ss. 45-51.

disclosure was in good faith.[54] If an employee employed as a health practitioner resigns or is dismissed from his or her employment for reasons of competence, then the employer must promptly give the registrar of the registration authority notice of the reasons for the resignation or dismissal. [55] Finally, if the Health and Disability Commissioner or the Director of Proceedings has concerns about the competence of a health practitioner he or she must also inform the registrar. If the registration body has reason to believe that a health practitioner may pose a risk of harm to the public, then the registrar must report these concerns to: the Accident Compensation Corporation, the Director-General of Health; the Health and Disability Commissioner; and any person who employs the health practitioner or is in partnership or association with that practitioner.[56]

An employer, health practitioner, head of an organization that employs health practitioners or a medical officer of health must advise the registrar of the relevant registration authority of any concerns that a practitioner is unable to fulfill the functions required of his or her profession because of a physical or mental condition.[57]

Complaints about a health care practitioner must be forwarded to the Health and Disability Commissioner (see Other Patient Complaints Mechanisms section).[58] The Commissioner can choose to deal with the complaint or to refer it back to the registration authority, which in turn may as one of its options refer the complaint to a professional conduct committee (PCC) for assessment and investigation.[59] Members of the PCC are appointed by the registration authority.[60] Within 14 days of completing an investigation, the PCC must choose from a number of determinations and recommendations specified in the Act.[61] The PCC can decide to lay charges before the disciplinary tribunal or to forward a complaint to conciliation. It may also determine that no further action is required under the Act.

Registration authorities are established as corporate bodies under the Act and are funded through fees collected from their members.[62] Authorities must submit an annual report to the Minister of Health at the end of each fiscal year.[63]

The Act establishes an independent Health Practitioners Disciplinary Tribunal to hear disciplinary proceedings brought against health practitioners. All members of the Tribunal are appointed by the Minister and Tribunal members cannot be members of the registration authorities.[64] The chairperson and deputy chairpersons must be senior

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[54] *Ibid.* at ss. 34(1), 34(4).
[55] *Ibid.* at ss. 34(3)-(4).
[56] *Ibid.* at ss. 35(1)-(2).
[57] *Ibid.* at s. 45.
[58] *Ibid.* at s. 64 (1).
[59] *Ibid.* at s. 65
[60] *Ibid.* at s. 71.
[61] *Ibid.* at s. 80.
[62] *Ibid.* at ss. 117. 130.
[63] *Ibid.* at s. 134.
[64] *Ibid.* at s. 86.

lawyers.[65] Other members are appointed from a panel of candidates (lay and health practitioners from each profession) maintained by the Minister. [66]

A professional conduct committee or the Director of Proceedings (a statutorily created independent prosecutor affiliated with and fiscally accountable to the Commissioner) can decide to lay charges before the Health Practitioners Disciplinary Tribunal.[67] When conducting a hearing, the Tribunal consists of the chairperson or a deputy chairperson, one lay person and three professional peers of the health practitioner concerned.[68] The Tribunal may suspend the practitioner or impose conditions on his or her practice before the hearing.[69] If the Tribunal finds the charges valid, it may cancel registration, suspend registration, place conditions on practice, censure the practitioner, fine him or her and make an order for costs.[70] A right of appeal exists to the High Court.[71]

Tribunal hearings must be held in public unless the Tribunal orders otherwise, having considered the interests of the persons involved and the public interest.[72] Registration authorities are responsible for funding the Tribunal.[73]

The *Health Practitioners Competency Assurance Act 2003* also contains provisions that allow health practitioners to apply to the Minister to have quality assurance activities (QAA) 'protected.'[74] Information that becomes known and documents that come into existence solely as a result of a protected quality assurance activity are confidential and immunity from civil liability is accorded to those who undertake quality assurance in good faith. The Act's QAA provisions apply to activities aimed at improving the practice and competence of health practitioners. They do not apply to activities with a specific systemic focus. The Minster may grant protection to an activity only after determining it is in the public interest to do so and there are reporting requirements for those undertaking protected activities.[75] The Minister may authorize the disclosure of information when it relates to a serious offence and is needed for criminal investigations and prosecutions or public inquiries.[76] Previously, quality assurance protection was only available to medical practitioners.

Given the newness of this legislation, the Act's effectiveness has not yet been assessed. However, the Act contains a mandatory review provision that requires the Director-

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[65] *Ibid.* at s. 38.
[66] *Ibid.* at s. 87.
[67] *Ibid.* at s. 91.
[68] *Ibid.* at s. 88.
[69] *Ibid.* at s. 93.
[70] *Ibid.* at s. 101.
[71] *Ibid.* at ss. 106(2)-(3).
[72] *Ibid.* at s. 95.
[73] *Ibid.* at s. 104.
[74] *Ibid.* at ss. 52-63.
[75] N.Z., Ministry of Health, "Protected Quality Assurance Activities Under the HPCA 2003" (June 2004), at 5-6, online: MOH <http://www.moh.govt.nz/moh.nsf/0/EFF89E424DA432F5CC256EBC00025C00/$File/protectedqualityassuranceactivities.pdf>.
[76] *Ibid.* at 6; *Health Practitioners Competency Assurance Act 2003*, *supra* note 33 at s. 61(1).

General of Health to review the operation of the Act three years after its coming into force.[77]

Products Regulation

Pharmaceuticals and medical devices are regulated by New Zealand Medicines and Medical Devices Safety Authority (Medsafe) a business unit of the Ministry of Health. Medsafe is funded through a mix of industry fees and Crown funding.[78] It is accountable to the Minister of Health.[79] Medsafe is "responsible for ensuring that, as far as possible, the medicines available in New Zealand can be expected to have greater benefits than risks if used appropriately."[80] This goal is achieved through:

- premarket assessments of the safety, quality and efficacy of medicines;
- postmarket monitoring of the safety of medicines;
- the auditing of manufacturers, packers and wholesalers of medicines to confirm their premises and practices meet acceptable standards. [81]

Medsafe administers the *Medicines Act 1981, Medicines Regulations 1984* and parts of the *Misuse of Drugs Act 1975* and the *Misuse of Drugs Regulations 1977.*

New Zealand has a voluntary adverse reaction reporting scheme for the monitoring of adverse reactions to medicines, vaccines and fractionated blood products.[82] The scheme is operated by the Centre for Adverse Drug Reactions (CARM) under the guidance of the Medicines Adverse Reactions Committee. The Medicines Adverse Reactions Committee is a ministerial advisory committee comprised of general practitioners, medical specialists and one clinical pharmacist.[83] The Centre is independent but has a funding contract with Medsafe. It receives information in relation to:

- all suspected reactions to new medicines;
- all suspected medicine interactions;

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[77] *Health Practitioners Competence Assurance Act 2003*, *ibid.* at s. 171.
[78] New Zealand Institute of Research, "Assessment of Regulatory Options for Therapeutic Products: Report to the Trans-Tasman Working Group" (Wellington: New Zealand Institute of Research Inc. 2002) online: TGA/Medsafe <http://www.tgamedsafe.org/about/0210costbenefit.htm>.
[79] New Zealand Medicines and Medical Devices Safety Authority, "Who We Are," online: Medsafe <http://www.medsafe.govt.nz/other.htm>.
[80] New Zealand Medicines and Medical Devices Safety Authority, "How Medicines Are Regulated," online: Medsafe <http://www.medsafe.govt.nz/cons.htm>.
[81] *Ibid.*
[82] *New Zealand Regulatory Guidelines for Medicines: Reporting Substantial Untoward Effects of Medicines* (N.Z.), 2001 at s. 19.1, online: Medsafe <http://medsafe.govt.nz/reg.htm> [*N.Z. Regulatory Guidelines for Medicines*].
[83] New Zealand Medicines and Medical Devices Safety Authority, "Adverse Event Reporting and IMMP: Pharmacovigilance in New Zealand," online: Medsafe <http://www.medsafe.govt.nz/profs.htm>.

- reactions to any medicines suspected of causing death, danger to life, admission to hospital or prolongation of hospitalization, persisting disability, significant intervention to manage the reaction, absence from productive activity, birth defects;
- all serious allergic reactions and all suspected adverse reactions listed in the *Prescriber Update* as *Adverse Reactions of Current Concern.*[84]

Reports from health practitioners are preferred and 65% of CARM's reports come from community doctors.[85] CARM will accept reports from consumers, but encourages the involvement of the patient's physician. CARM sends responses to those reporting adverse events, which may include causality information and prescription advice. New Zealand claims to have the best reporting rates internationally for voluntary systems.[86]

The Centre for Adverse Reactions Monitoring collects and evaluates adverse effects information in a database. It also uses the patient's national health index number to record a danger alert for severe and life-threatening reactions so that when the patient is next seen and the system accessed the information is displayed and incorporated into the facility's 'alert' mechanism. The Centre analyses database information on a regular basis and reports patterns to the Medicines Adverse Reactions Committee which in turn makes recommendations to Medsafe. Medsafe has the responsibility to implement strategies for the safer use of the medicines concerned.[87]

There is also a more proactive mechanism for adverse effects monitoring. The Intensive Medicines Monitoring Programme (also administered by the Centre for Adverse Reactions Monitoring) monitors a small number of medicines, usually novel agents (i.e. new drug class).[88] The programme's purpose is to identify unrecognized adverse reactions, high risk groups and characterizing reactions of clinical concern.[89] It is a voluntary system and doctors and pharmacists are requested to submit details of a patient's prescriptions and all adverse clinical events. A review of the need for monitoring occurs after two years.[90] However, the program is currently under review, which has attracted international concern that funding will be cut and the program extensively modified.[91] The New Zealand government states that its intent is to 'modernise' the programme.

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[84] *N.Z. Regulatory Guidelines for Medicines*, *supra* note 82.
[85] Centre for Adverse Reactions Monitoring, "Guide to Adverse Reaction Reporting," online: CARM <http://carm.otago.ac.nz/pdfs/Guide%20to%20adverse%20reacation%20reporting.PDF>.
[86] *Ibid.*
[87] *Ibid.*
[88] *N.Z. Regulatory Guidelines for Medicines*, *supra* note 82 at s. 19.2
[89] New Zealand Medicines and Medical Devices Safety Authority, "Prescriber Update: June 2005" (2005) 26:1 at 18, online: Medsafe < http://www.medsafe.govt.nz/profs.htm>.
[90] *N.Z. Regulatory Guidelines for Medicines*, *supra* note 82 at s. 19.2.
[91] Andrew Herxheimer, "Open Letter to Annette King, Minister of Health New Zealand" (2004) 329 BMJ 51; Don Matheson, "Minister's Response" (2004) 329 BMJ 51; Michael Jenkinson, "Re: Minister's Response" (2004) 329 BMJ 51.

Manufacturers or importers of medicines are required under section 41 of the *Medicines Act* to report any substantial adverse effects that arise in New Zealand or overseas.[92]

Medical device regulation in New Zealand was characterized in 2003 as being "out of step with international practice."[93] The system lacked minimum safety, quality and performance standards for devices, a pre-market risk assessment mechanism and a register for products on the market that would enable the tracing and recall of defective devices. Since then, the government has passed the *Medicines (Database of Medical Devices) Regulations 2003*.[94] The regulations require manufacturers or importers of medical devices for use in New Zealand to enter details concerning their device onto an electronic notification database within 30 days of commencing supply.[95] The risk classification for each device must be entered into the database using the Global Harmonisation Task Force (GHTF) risk classification system for medical devices.[96] This step is meant to facilitate the transition to the planned joint regulatory agency for therapeutic products with Australia and the adoption of a joint risk based GHTF framework for medical device regulation.[97]

In December of 2003, the Australian and New Zealand governments signed a treaty that calls for the establishment of a joint scheme consistent with international best practice for the regulation of the quality, safety and efficacy of therapeutic products.[98] The scheme will use risk-based regulation for therapeutic products, including complementary medicines.[99] The treaty outlines the broad governance and accountability framework of the scheme and mandates the creation of a Merits Review Tribunal with the power to reconsider the Joint Agency's decisions regarding product approvals.[100] Joint mechanisms are expected to be in place for the licensing of manufacturers, the pre-market assessment and post-market monitoring of products and enforcement.[101] Consultation continues and draft implementing legislation and regulations containing details of the

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[92] *N.Z. Regulatory Guidelines for Medicines*, *supra* note 82 at s. 19.3.2.
[93] Australia New Zealand Therapeutics Products Authority, "Fact Sheet 2: Rationale for the Joint Scheme," online: Trans-Tasman Therapeutic Products Agency Project <http://www.jtaproject.com/Downloads/Key%20Documents/factsheets1to5.pdf>.
[94] (N.Z.), 2003/325.
[95] New Zealand Medicines and Medical Devices Safety Authority, "Letter Sent To Device Suppliers, November 2003," online: Medsafe <http://www.medsafe.govt.nz/WANDPage.htm>.
[96] New Zealand Medicines and Medical Devices Safety Authority, "An Introduction To WAND: The Web-Assisted Notification of Devices Databases," at 5, online: Medsafe <http://www.medsafe.govt.nz/WANDPage.htm>.
[97] Marilyn Anderson, "The Trans Tasman Therapeutic Products Scheme" (Presentation at the In-Vitro Diagnostics Seminar, December 2004) at slide 12, online: Medsafe <http://www.medsafe.govt.nz/Regulatory/wand.htm>.
[98] *Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products*, Australia and New Zealand, 28 March 1983, online: Trans-Tasman Therapeutic Products Agency Project <http://www.jtaproject.com/key.htm> [*Agreement*].
[99] Australia New Zealand Therapeutics Products Authority, "Fact Sheet 3: How Will Therapeutic Products Be Regulated Under the Joint Scheme," online: Trans-Tasman Therapeutic Products Agency Project <http://www.jtaproject.com/Downloads/Key%20Documents/factsheets1to5.pdf> [Fact Sheet 3].
[100] *Agreement*, *supra* note 98 at art. 4-8, s. 13.
[101] *Ibid.* at art. 3(1); Fact Sheet 3, *supra* note 99.

joint regulatory scheme are expected sometime before July of 2006, the operational deadline set for the Agency.[102]

Inquiry Processes

There is a provision in the *New Zealand Public Health and Disability Act 2000* for the Minister to authorize the commencement of inquiries and investigations pursuant to the *Commissions of Inquiry Act 1908*[103] i.e. independent commissions of inquiry. Ministerial initiated inquiries are less common than they once were because of the role of the Health and Disability Commissioner and the Mental Health Commission, but still occur on rare occasions. The most recent Ministerial inquiry was into the cervical cancer program in the Gisborne region in 2001.[104]

The Coroner's process also plays a role in investigating medical error in New Zealand. It seems there is an increasing trend to conduct a coronial inquiry in respect of medical misadventures.[105] The Law Commission of New Zealand recently conducted a review of Coronial practices[106] and noted:

> In recent years, the role of the Coroner has increasingly been recognized as one in which the thorough investigation of a death can lead to a reduction in future injury and preventable deaths.
>
> However, the ability of Coroners to fulfill their many functions and in particular to assist in death and injury prevention, and thus influence the development of public health policy, has been limited by … systemic problems ….
>
> Under the present haphazard regime there is no centralized recording system which would allow patterns to be discerned and responded to, nor any Chief Coroner, suitably resourced to devise and maintain the necessary systems to

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[102] New Zealand Medicines and Medical Devices Safety Authority, News Release, "Australia, New Zealand Announce Start-Up Date for Joint Therapeutic Products Agency" (10 February 2005), online: Medsafe < http://www.medsafe.govt.nz/hot.htm>. See also Trans-Tasman Therapeutic Products Agency Project, online: <http://www.jtaproject.com/key.htm> for various consultation documents and reports.
[103] (N.Z.), 1908/25.
[104] New Zealand, Ministerial Inquiry, *Report of the Ministerial Inquiry into the Under-Reporting of Cervical Smear Abnormalities in the Gisborne Region*" by A. Duffy, P. Barrett, & M. Duggan (Wellington: New Zealand Ministry of Health and Gisborne Cervical Screening Inquiry, 2001) online: Cervical Screening Inquiry <http://www.csi.org.nz/report/table_of_contents.htm>.
[105] Bruce Corkill, "Medical Misadventure – Development of the Statutory Concept and its Place in the Current Medico-Legal Environment" (2002) at 32, online: ACC <http://www.acc.co.nz/wcm001/idcplg?IdcService=SS_GET_PAGE&nodeId=3879&ssSourceNodeId=1494>.
[106] The Law Commission, *Coroners* (Wellington: The Law Commission of New Zealand, 2000), online: The Law Commission < http://www.lawcom.govt.nz/ProjectReport.aspx?ProjectID=70>.

> oversee Coroners and to monitor the implementation of coronial recommendations.[107]

In November 2004, a new *Coroners Bill* was introduced into Parliament that draws on recommendations from the Law Commission and a government review of the coronial system.[108] The purpose of the proposed Act is the prevention of deaths through investigations and the making of public recommendations aimed at reducing reoccurrence.[109] All maternal deaths and deaths that occur during or appear to result from medical, surgical or dental procedures would be reported.[110]

It is also important to note that New Zealand Police use criminal law processes, specifically provisions in relation to manslaughter and failing to provide the necessities of life, to prosecute some doctors whose patients die in their care as a result of alleged negligence. For some years, the standard required for criminal liability was mere negligence. However, reforms changed the standard required to gross negligence. Prosecutions are now less frequent in number, but still occur.[111]

Compensation Systems

New Zealand has a no fault national insurance system for personal injuries, including those arising from medical treatment. In 1967 a Royal Commission was established as a result of complaints about the inadequacy of workers compensation benefits. The report of the Royal Commission recommended a completely no-fault approach to compensation for personal injury.[112] It recommended a scheme to cover all motor vehicle injuries and all injuries whether at work or not. The right to sue for personal injury would be removed. The Report recommended that the scheme be based on five basic principles:

- community responsibility;
- comprehensive entitlement;
- complete rehabilitation;
- real compensation; and
- administrative efficiency.

The accident compensation scheme was introduced in 1974 and is administered by the Accident Compensation Corporation (ACC), a crown entity. The scheme provides personal injury coverage for all New Zealand citizens, permanent residents, and visitors

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[107] *Ibid* at xi.
[108] N.Z., Bill 228-1, *Coroners Bill*, 2004, online: Knowledge Basked <http://www.knowledge-basket.co.nz/gpprint/docs/bills/20042281.txt> [*Coroners Bill*].
[109] *Ibid.* at cl. 3.
[110] *Ibid.* at cl. 11.
[111] Alan Merry & Alexander McCall-Smith, *Errors, Medicine and the Law* (Cambridge: Cambridge University Press, 2001).
[112] New Zealand, Royal Commission of Inquiry on Compensation for Personal Injury in New Zealand, *Report of the Royal Commission of Inquiry on Compensation for Personal Injury in New Zealand* by Hon. Justice Woodhouse, (Wellington: Government Printing Office, 1967) [Woodhouse Report].

to New Zealand. In exchange, individuals do not have the right to sue, other than for exemplary damages. Currently, the *Injury Prevention Rehabilitation and Compensation Act 2001* (IPRC Act) sets the framework for the provision of national no-fault insurance. The Act establishes injury prevention as a primary function of the ACC and creates a framework for integrating injury related information from different agencies. Rehabilitation entitlements include treatment and both social and vocational rehabilitation. Claimants who qualify are to receive fair compensation for loss due to injury, usually in the form of weekly compensation during rehabilitation or a lump sum payment for permanent injury.

The scope of ACC coverage for injuries caused by medical treatment, or medical misadventure, has changed over time. In 1992, new legislation formalized scheme boundaries in response to concerns over expenditures and increasing legal challenges.[113] Medical misadventure was defined in the legislation as personal injury caused by either medical mishap or medical error. Medical mishap occurred when the correct treatment was properly given, but there was a complication that was both rare (one percent or fewer people would have the complication from the treatment) and severe (in hospital for at least 14 days, significant disability for at least 28 days or death). Medical error happened when the injured person did not receive treatment of a reasonable standard given the circumstances, including a failure to diagnose, obtain informed consent or provide treatment. Medical error cases had to be reported to the Health and Disability Commissioner and the appropriate disciplinary body and the ACC had discretion to report medical mishap. However, these definitions and the reporting requirement created problems and inequities in the scheme.

In 2001, the Government launched an internal review of the medical misadventure provisions and a number of problems were identified. The requirement to find fault under the medical error provision was felt to be at odds with the no-fault system, inconsistent with approach to patient safety being promoted in the health sector, and a hindrance to the claims process.[114] The emphasis on finding fault and reporting made health professionals reluctant to be involved in the claims process and lead to defensiveness and difficulty in obtaining information. Medical mishap criteria were felt to be arbitrary and confusing, as they often bore little relation to the patient's circumstances and resulted in patients being unfairly denied coverage. Statistics indicate that around 60% of medical misadventure claims failed to meet the legislative criteria compared to less than 1% of all other accidental injury claims. Also, while most other claims were decided immediately, medical misadventure claims often took several months, causing significant delays in access to rehabilitation and compensation for injured patients. [115]

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[113] Cathy Scott, "Time for Fine-Tuning: The Review of the No Fault Medical Misadventure Scheme in New Zealand 2004/5" (Lecture to the OECD, June 2005) [unpublished] [Time for Fine-Tuning].
[114] N.Z., Office of the Minister for ACC, *Medical Misadventure Review – Conclusions and Recommendations* (Wellington: New Zealand Government, 2004) at 7 [*Medical Misadventure Review – Conclusions and Recommendations*]; N.Z., Bill 593/6. *Injury Prevention, Rehabilitation, and Compensation Amendment Bill (No 3)*, 2004 at Explanatory Note.
[115] Time for Fine-Tuning, *supra* note 113. See *Injury Prevention, Rehabilitation, and Compensation Act 2001* (N.Z.), 2001/49 at s. 57(1)(c) [*Injury Prevention, Rehabilitation, and Compensation Act 2001*], where

In May 2005, the *Injury Prevention, Rehabilitation, and Compensation Amendment Act (No. 2) 2005* was passed to implement changes aimed at making ACC's medical misadventure provisions simpler and fairer and improving patient safety.[116] The old medical misadventure provisions are replaced by a new 'treatment injury' category.[117] Determinations of fault, rarity and severity are removed from the process and instead, an injury must be caused as a result of seeking or receiving treatment to be covered. The treatment must be provided by a registered health professional and claims are not covered if the personal injury is:

- a necessary part or ordinary consequence of the treatment (ie. surgical incisions);
- caused by the patient's underlying condition;
- caused by the patient's unreasonable withholding or delaying of consent;
- solely attributable to a resource allocation decision (waiting lists).[118]

In addition, claims cannot be based solely on the fact that the desired result was not achieved. The definition of "treatment" includes:

- diagnosis;
- failure/omission to treat in a timely manner;
- equipment failure;
- medical device failure (including latent);
- clinical trials;
- support systems for treatment used by the organization or individual (i.e. policies, processes, practices and administrative systems that directly support the treatment provided).[119]

These definitional changes acknowledge system errors and seem to reflect the "widespread recognition that injuries caused by treatment are seldom the result of the actions of a single individual, but rather reflect the interactions between individuals, systems and policies intrinsic to the provision of health care."[120] By removing the focus on individual fault, the new scheme is aimed at making health professionals more willing to cooperate with the claims process, discuss medical injuries and learn from them.[121]

The Act also includes reforms to the reporting requirements that seek to protect public safety while changing "the punitive system of finding and reporting medical error."[122] Under the new provisions, the ACC will no longer have to routinely report practitioners

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the ACC is given a maximum of 9 months to decide complicated medical misadventure claims. The same time limit applies to decisions under the new treat injury provisions.

[116] New Zealand Medicines and Medical Devices Safety Authority, News Release, "'Treatment Injury' to Replace ACC Medical Misadventure" (16 March 2004) [Treatment Injury].

[117] *Injury Prevention, Rehabilitation, and Compensation Act 2001*, *supra* note 115 at s. 32.

[118] *Ibid.* at s. 32(2); N.Z., Office of the Minister for ACC, *Medical Misadventure Review: Further Issues Associated with the Change from Medical Misadventure to Treatment Injury* (Wellington: New Zealand Government, 2004) at para. 14, 16.

[119] *Injury Prevention, Rehabilitation, and Compensation Act 2001*, *supra* note 115 at ss. 32(4), 33.

[120] *Medical Misadventure Review – Conclusions and Recommendations*, *supra* note 114 at 5.

[121] Treatment Injury, *supra* note 116.

[122] *Ibid.*

involved in error claims to the HDC or the registration authorities. Instead, if the ACC believes there is a risk of harm to the public, it must report that risk and other relevant information to the appropriate authority responsible for patient safety, depending on whether that risk involves an organization, a procedure, equipment or an individual.[123] The ACC is currently developing operational policy in this area and they will report all sentinel and serious events.[124] However, it is unclear whether the individuals or organizations will be identified in these harm reports, where the claim information collected is focused on what happened to the patient and not the treatment process itself.[125] As an additional accountability measure, all persons who lodge a claim for treatment injury must be advised by the ACC of the role of the Health and Disability Commissioner.[126] Thus the role of Accident Compensation Corporation is to focus on injury prevention, rehabilitation and compensation for injury suffered by the patient, rather than assessing whether a health care provider's care was of a reasonable standard.

As part of its injury prevention function, the ACC issues reports on the most common types of unintended injuries and strategies to reduce or prevent them.[127] It also issues guidelines to prevent injuries[128] and best practice guidelines for the treatments of particular injuries.[129] It may contribute articles to medical journals relating to patterns of claims. It works with District Health Boards to disseminate information (including providing an individual report on claims patterns).

Under the IPRC Act, the ACC is required to enter into an annual service agreement with the Minister concerning the quality and quantity of services purchased or provided by the ACC.[130] The Minister responsible for the ACC has used this contractual mechanism to have the ACC undertake operational initiatives to support quality improvement in the health care sector.[131] These initiatives are targeted at using claim information to aid in the prevention of adverse medical events. They include the continued provision of reports on patterns of claims to interested bodies such as employers and medical colleges and the provision of greater access to anonymised information on ACCs database to individuals or institutions involved in quality improvement.[132] The ACC has also established a patient safety program aimed at reducing preventable treatment injuries and sharing

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[123] *Injury Prevention, Rehabilitation, and Compensation Act 2001*, *supra* note 115 at s. 284; *Medical Misadventure Review – Conclusions and Recommendations*, *supra* note 114 at 15.
[124] Accident Compensation Corporation, *Business Plan 2005-2006* (2005) at 6.
[125] *Medical Misadventure Review – Conclusions and Recommendations*, *supra* note 114 at 15.
[126] *Injury Prevention, Rehabilitation, and Compensation Act 2001*, *supra* note 115 at s. 50(2).
[127] For example, the ACC has recently issued a report on wrong-site surgery.
[128] Accident Compensation Corporation, "The New Zealand Patient Handling Guidelines," online: ACC < http://www.acc.co.nz/wcm001/idcplg?IdcService=SS_GET_PAGE&nodeId=4148>.
[129] S. Cartwright, *The Report of the Committee of Inquiry into Allegations Concerning the Treatment of Cervical Cancer at National Women's Hospital and Into Other Related Matters.* Auckland: Government Printing Office, 1988 [Cartwright Inquiry].
[130] *Injury Prevention, Rehabilitation, and Compensation Act 2001*, *supra* note 115 at s. 271.
[131] Accident Compensation Corporation, *Service Agreement 2004/05 between the Minister for ACC and ACC*, at 6, online: ACC <http://www.acc.co.nz/wcm001/groups/external_communications/documents/internet/wcm2_020653.pdf>.
[132] *Medical Misadventure Review – Conclusions and Recommendations*, *supra* note 114 at 16.

information. It has created a Patient Safety Team who is responsible for tracking trends and generating reports based on their database of adverse medical events claims.[133]

The ACC is accountable to the government through a variety of contracts that outline key strategies and performance indicators that the ACC is expected to meet each year.[134] The ACC is run like a corporation with a Board of Directors appointed by the Minister responsible for the ACC. The scheme is funded through premiums whose levels are set by the government. The Medical Misadventure account receives funds from the government on behalf of non-earners and premiums collected from all working New Zealanders.[135] Under the old system, the account had costs of 47 million New Zealand dollars per year and approximately 1000 to 2000 medical misadventure claims were accepted each year.[136] Changes under the new legislation are expected to add 8.69 million New Zealand dollars in costs, but the net benefits of increased cover, fairer and quicker ACC decision-making and a system that contributes to a healthcare learning culture are thought to outweigh the costs.[137]

Other Patient Complaint Mechanisms

The office of Health and Disability Commissioner (HDC) is an independent statutory agency that was created in 1994 as a result of recommendations in the Cartwright Report.[138] Its purpose is to "promote and protect the rights of health consumers and disability services consumers, and to that end, to facilitate the fair, simple, speedy, and efficient resolution of complaints relating to infringements of those rights."[139]

The legal framework for the work of the Commissioner is provided by the *Health and Disability Commissioner Act 1994* and the *Code of Health and Disability Services Consumers' Rights 1996*.[140] Under the Act, the Commissioner can investigate complaints against persons, institutions or bodies that provide health or disability services where it is alleged that there has been a breach of the Code.[141] The Act covers both public and private providers. The Commissioner's jurisdiction does not include matters of funding or entitlement to services.

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[133] Accident Compensation Corporation, "Patient Safety," online: ACC <http://www.acc.co.nz>.
[134] Accident Compensation Corporation, "ACC Accountability Documents," online: ACC <http://www.acc.co.nz>.
[135] Accident Compensation Corporation, "How the ACC is Funded," online: ACC <http://www.acc.co.nz>.
[136] *Medical Misadventure Review – Conclusions and Recommendations*, *supra* note 114 at 18.
[137] *Medical Misadventure Review – Conclusions and Recommendations*, *supra* note 114 at 28.
[138] Cartwright Inquiry, *supra* note 129.
[139] *Health and Disability Commissioner Act 1994* (N.Z.), 1994/88 at s. 6 [*Health and Disability Commissioner Act 1994*].
[140] *Ibid.* at s. 1; *Health and Disability Commissioner (Code of Health and Disability Services Consumers' Rights) Regulations 1996* (N.Z.), 1996/78, Sch. I [*Health and Disability Commissioner Regulations*].
[141] *Health and Disability Commissioner Act 1994*, *supra* note 139 at s. 40(1).

The Code is a regulation that sets out ten consumer rights which providers are required by law to comply with. The rights include:

- The Right to Be Treated with Respect
- The Right to Freedom from Discrimination, Coercion, Harassment and Exploitation
- The Right to Dignity and Independence
- The Right to Services of an Appropriate Standard
- The Right to Effective Communication
- The Right to be Fully Informed
- The Right to Make an Informed Choice and Give Informed Consent
- The Right to Support
- Rights in Respect of Teaching and Research
- The Right to Complain

Under the Code, consumers have the right to services of an appropriate standard, which includes "the right to have services provided in a manner that minimises the potential harm to, and optimises the quality of life of, that consumer" and "the right to co-operation among providers to ensure quality and continuity of services."[142] The Code also creates a right to complain for consumers and states that every provider must have a complaint procedure. As part of their procedure, providers are required to acknowledge the complaint within five working days and they have a further 10 days to decide whether the complaint is justified, not justified or requires further investigation. [143] However, the Code's rights are not absolute. If a provider can demonstrate they have taken reasonable steps to give effect to the rights given all the relevant circumstances – including "the consumer's clinical circumstances and the provider's resource constraints," the provider will not have breached the Code.[144]

The functions of the office are to: act as the gatekeeper for complaints about health service providers; resolve complaints at the lowest appropriate level; and to educate consumers and providers about the rights of consumers and providers' responsibilities under the Code.[145] The office focuses on the acts or omissions of individuals and institutions. The HDC is not required to establish a causative link between a breach of standards and a physical injury. The mere fact that a breach of a standard has occurred is enough. After conducting a preliminary assessment of a complaint, the Commissioner may decide that no further action is warranted. A complaint may be referred to other appropriate agencies, including the provider so long as the complaint does not raise concerns about the health and safety of the public.[146] Additional options involve investigation, mediation and facilitating an apology to the consumer or other remedies. The Commissioner does not have the power to grant compensation. Complaints can also be referred to an independent advocacy service administered by the HDC. Once the Commissioner concludes an investigation, he or she may choose to refer the matter to the

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[142] *Health and Disability Commissioner Regulations*, *supra* note 140 at ss. 4(4)-(5).
[143] *Ibid.* at ss. 10(6)-(7).
[144] *Ibid.* at s. 3.
[145] *Health and Disability Commissioner Act 1994*, *supra* note 139 at s. 14.
[146] *Health and Disability Commissioner Act 1994*, *supra* note 139 at s. 34.

Director of Proceedings, a statutorily independent prosecutor who determines whether to take the case to disciplinary proceedings or before the Human Rights Review Tribunal.[147] After an investigation, the Commissioner makes his findings publicly available, usually in the form of an anonymised report.

The Commissioner also plays a role in quality improvement at both the individual and systems level.[148] The ability to investigate health care organizations for breaches of the Code allows the Commissioner to address how systems issues impact on quality of care and the Commissioner can recommend an organization review its practices or provide its staff with additional training. The Commissioner sends important reports to key agencies and professional bodies and advocates on behalf of consumers for change.[149] There is evidence that providers are increasingly using these reports for educational and quality improvement purposes.[150]

While recognizing that complaints can be "a window of opportunity" for improving the quality of health care, the current Commissioner, Ron Patterson, has noted that "complaints can have toxic effects on health professionals and patients" and should be handled with care. [151] Responses to HDC's 2003/2004 satisfaction survey highlighted the stress felt by both groups during the investigation process and the need for quicker timeframes for investigations.[152] A 2001 study involving 971 New Zealand doctors indicated that while the majority of doctors supported society's right to complain, complaints can have a significant immediate emotional impact on doctors and their suggestions for change included: the rapid resolution of complaints, a complaints process focused on improving medical practice, and a process that facilitated dialogue through the greater use of low level mechanisms such as mediation.[153] In 2001, the Cull Report stated that the complaints system in New Zealand, with its multiple complaint processes,

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[147] The Human Rights Review Tribunal can hear cases involving institutions, non-registered health practitioners and registered health practitioners. It can grant compensation in limited situations.

[148] See The Health and Disability Commissioner, Case 03HDC10460 and Case 03HDC03134, online: HDC <http://www.hdc.org.nz/casenotes.php?year=2003>, for examples of the Commissioner's reports that address quality of care issues at both levels.

[149] The Health and Disability Commissioner, "A Review of The Health and Disability Commissioner Act 1994 and the Code of Health Disability Services Consumers' Rights: A Resource for Public Consultation" (2004), online: HDC < http://www.hdc.org.nz/theact.php?content=19> at 11 [Review of HDCA and CHDSCR]; The Health and Disability Commissioner, "Annual Report For the Year Ended 30 June 2003" (2003), online: HDC <http://www.hdc.org.nz/files/pagepublications/report2004.pdf>, at 2 [Annual Report].

[150] Review of HDCA and CHDSCR, *ibid.* at 11. This evidence is anecdotal in nature (Correspondance from Nicola Sladden, HDC Legal Manager (August 2005).

[151] Annual Report, *supra* note 149 at 1.

[152] *Ibid.* at 34.

[153] Wayne Cunningham, "The Immediate and Long-Term Impact on New Zealand Doctors Who Receive Patient Complaints" (2004) 117:1198 N Z Med J. U972; Wayne Cunningham, "New Zealand Doctors' Attitudes Towards the Complaints and Disciplinary Process" (2004) 117:1198 N Z Med J. U973; Wayne Cunningham, "The Medical Complaints and Disciplinary Process in New Zealand: Doctors' Suggestions for Change" (2004) 117:1198 N Z Med J. U974 The New Zealand Medical Journal, 23 July 2004, vol 117, no 1198.

time delays and access problems, was "confusing, cumbersome, difficult to access and costly, both financially and emotionally."[154]

In force since 18 September 2004, the *Health and Disability Commissioner Amendment Act 2003* incorporates many the report's recommendations. The Act designates the HDC as the initial recipient of complaints, establishes clearer lines of responsibility and co-operation between agencies regarding complaints, and gives the Commissioner more flexibility in dealing with complaints. Previously, the Commissioner had to investigate all complaints unless he or she referred it to an advocate or decided to take no action.[155] Under the new Act, the Commissioner conducts preliminary assessments and can choose from low level resolution mechanisms such as mediation in addition to investigation. It is anticipated that these changes will help simplify and speed up the complaint resolution process.[156]

Adverse Event Reporting Systems

To date there is no national mandatory or voluntary reporting system for adverse events resulting from the provision of health services (with the exception of medications discussed above).

In 2000, the Ministry of Health assembled a working party to make recommendations on the feasibility of starting a national mandatory adverse event reporting system. In their report, *Towards Clinical Excellence: Learning from Experience*, the working party recommended that a national mandatory reporting system be developed for a defined list of serious or sentinel events.[157] These events would be reported to and analyzed by an independent national committee, who would create strategies for national learning. The system would be implemented legislatively and would include legal protection for information provided to the committee. The report noted that while many organizations (Ministry of Health, ACC, HDC, registration authorities, coroner, etc) have important data, there exists no central system for events to be collectively tracked or analyzed.[158] The benefits of a new system included fewer deaths, increased public confidence, reduced hospital stays, and increased funds for service delivery due to enhanced effectiveness, while the costs included administrative oversight costs and initial set up

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[154] N.Z., Ministry of Health, *Review of Processes Concerning Adverse medical Events*, by Helen Cull (Wellington: Ministry of Health, 2001) at 15, online: MOH < http://www.moh.govt.nz/moh.nsf/ea6005dc347e7bd44c2566a40079ae6f/9565e9869641cd26cc256a1d0074172b/$FILE/cullreport3.pdf >.

[155] *Ibid.* at 16.

[156] The Health and Disability Commissioner, News Release, "HDC Annual Report 2004" (19 October 2004), online: HDC < http://www.hdc.org.nz/page.php?&page=publications&type=4>.

[157] N.Z., Ministry of Health, *Toward Clinical Excellence: Learning from Experience, A Report to the Director-General of Health* (Wellington, Ministry of Health, 2001) at v, 34-36, online: MOH <http://www.moh.govt.nz/moh.nsf/ea6005dc347e7bd44c2566a40079ae6f/008deb2fa836ba68cc256ad000804456?OpenDocument>.

[158] *Ibid.* at 18, 22.

costs to make providers' internal systems compliant.[159] No such legislated national reporting system has been implemented as yet, but in response to the report, the Ministry of Health released in 2001 updated reportable events guidelines and a sentinel events workbook for the sector to use when investigating adverse events.[160]

Other Legislative Instruments

The National Cervical Screening Programme (NCSP) was restructured to meet the requirements for an effective organized-population health program after the report of the Ministerial Inquiry into the Under-reporting of Cervical Smear Abnormalities in the Gisborne Region severely criticized the system for having lax safety monitoring.[161] Parliament passed the *Health (National Cervical Screening Programme) Amendment Act 2004* to address these concerns. In addition to providing new measures for reviewing the programme's safety and quality, the Act also allows for the incorporation of standards by reference, which would make standards enforceable if required.[162] The National Screening Unit is a separate unit within the Ministry of Health that sets quality standards for the national breast screening and cervical cancer screening programmes.[163] They are minimum standards that providers of the programmes should comply with and provider performance is monitored against them.

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[159] *Ibid.* at 24-25.

[160] N.Z., Ministry of Health, News Release, "Health Care Will Improve With New Ways of Investigating Events" (24 September 2001), online: MOH <www.moh.govt.nz>; Minister of Health (NZ), *Reportable Events Guidelines* (Wellington, Ministry of Health, 2001), online: MOH <www.moh.govt.nz>; Standards New Zealand, "Sentinel Events Workbook –Process for Standardized Investigation and Reporting in the Health Sector" (2001) SNZ HB 8152:2001, online: Standards New Zealand <http://www.standards.co.nz/default.htm>.

[161] Cervical Screening Inquiry, *supra* note 104.

[162] New Zealand, National Cervical Screening Programme, *Health (National Cervical Screening Programme) Amendment Act 2004: Factsheet* 2 online: National Cervical Screening Program <http://www.healthywomen.org.nz/NCSP/registry.aspx#>.

[163] N.Z., Ministry of Health, "Programme Monitoring," online: MOH <http://www.moh.govt.nz/moh.nsf/f872666357c511eb4c25666d000c8888/ba8c013755341b94cc256ec400003e60?OpenDocument>.

Patient Safety Law:
From Silos to Systems

Appendix 2: Country Reports
THE UNITED KINGDOM

Jocelyn Downie
William Lahey
Don Ford
Elaine Gibson
Mary Thomson
Tom Ward
Fiona McDonald
Alison Shea

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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The United Kingdom

The United Kingdom is a constitutional monarchy. Whilst formerly the United Kingdom was a unitary state, parliaments in Northern Island and Scotland in particular have substantial devolved powers, especially in regard to social services. The Parliament in Wales has less power. Local government also plays a greater role than in many other countries. The population of the United Kingdom is 59.2 million (England 49.6 million, Wales 2.9 million, Northern Ireland 1.7 million and Scotland 5 million).

Health Care System Context

Law

England and Wales use a common law system. Scotland uses a civil law system for the most part.

Health

NHS established

In 1946 the government created the National Health Service (NHS). In one stroke the government nationalized 1000 voluntary hospitals (i.e., charity hospitals) and 540 hospitals operated by local authorities to provide free hospital care. The government also made a commitment to fund free general practitioner care. In the 1946 Act the Minister is charged with the duty "to promote the establishment in England and Wales of a comprehensive health service designed to secure improvement in the physical and mental health of the people of England and Wales and the prevention, diagnosis and treatment of illness and for that purpose to provide or secure the effective provision of services [free of charge]". The private sector continued to have a role in the provision of health services in the United Kingdom working parallel to the nationalized system. The National Health Service funded, purchased, planned, managed and provided health services.

The Department of Health is under the direction of the Secretary of State for Health and five ministerial colleagues are responsible for health and personal social services in England. The Department sets overall health policy, including public health and the health consequences of environmental and food matters. It also has overall responsibilities for the NHS. Within the Department there are a series of groups and divisions with specific area or professional responsibilities (e.g., the public health group),

there is the office of the Chief Medical Officer, which provides expert medical advice, and the NHS Executive which provides leadership and central management functions.

The Conservative Government 1980s-1990s

The health system changed little until the 1980's when the Conservative government of the time implemented significant changes. Efficiency became the major theme in policymaking. Reforms had also occurred to the managerial style in the health system. It moved from consensus to contract and managers increasingly came from outside the health sector. The government aimed to reduce the role of government but paradoxically in doing so increased the role of the state.[1] The *National Health Services and Community Care Act 1990* introduced an internal market in the NHS. The purchasing of health services was separated from the provision of health services. District health authorities were to purchase health services and hospitals and community services were to provide them. The budgets assigned to the providers were to depend upon the provider's ability to be competitive and to attract contracts from purchasers. Purchasers included health authorities and GP fund-holders who were assigned a budget to purchase health services for their patients. Competition was thought to add a financial incentive to encourage those working in the NHS to make more efficient use of tax-payers' funds. Competition worked to an extent in London, but did not succeed in rural areas due to geographical monopolies. The Regional Health Authorities carried out a range of monitoring and performance management roles on behalf of the NHS Executive. Each District Health Authority had a contract with the Regional Health Authority specifying its tasks. NHS Trusts were also established and these Trusts were similarly accountable to Regional Authorities. In 1994 the Regional Health Authorities became regional offices of the NHS Executive strengthening the link between the centre and the regions.

The Labour Government 1990s

The Labour government implemented significant changes when it was elected into office. The 1997 White Paper *The New NHS*[2] set out a ten year plan for the future direction of the National Health Service in the United Kingdom. The White Paper suggested that the former system of the internal market in health care should be replaced with "'integrated care', based on partnership and driven by performance."[3] There are six principles that underlie the pledge:

1. to renew the NHS as a national service so that patients get fair access to consistently high quality, prompt and accessible services across the country;
2. to make the delivery of healthcare against these standards a matter of local responsibility;
3. to get the NHS to work in partnership and place the patient at the centre of the care process;

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[1] Rudolf Klein, *The New Politics of the National Health Service*, 4th ed. (New Jersey: Prentice Hall, 2000).
[2] U.K., Department of Health, *The New NHS: Modern, Dependable* (London: Department of Health, 1997).
[3] *Ibid.*, s. 1.3.

4. to drive efficiency through a more rigorous approach to performance and by cutting bureaucracy;
5. to focus on quality of care so that excellence is guaranteed to all patients and quality is the driving force behind all decision-making;
6. to rebuild public confidence in the NHS as a public service accountable to patients, open to the public and shaped by their views.[4]

Separation between planning of hospital care and its provision was maintained. Primary Care Trusts were established to replace GP fund-holding plans. Primary Care Trusts hold funds for general medical services, cash limited allocations, hospital and community health services and prescribing.

The White Paper called for the creation of National Service Frameworks which will bring together the best evidence of clinical and cost-effectiveness with the views of service users to determine the best ways of providing particular services. This includes explicit quality standards in local service agreements and a new system of clinical governance in NHS Trusts and Primary Care Trusts. This Framework aims to ensure that clinical standards are met and that processes are in place to ensure continuous quality improvement backed by a statutory duty of quality in NHS Trusts. The White Paper also called for the establishment of the National Institute for Clinical Excellence and the Commission for Health Improvement. Under the new service configuration NHS Trusts are statutorily accountable to the NHS Executive, health authorities to regional offices of the NHS Executive and Primary Care Trusts to the health authorities. Service accountabilities also flow between health authorities and NHS Trusts and NHS Trusts and Primary Care Groups.

According to the White Paper, Health Authorities are given additional powers to improve health and to oversee the effectiveness of the NHS locally. They will take the lead in drawing up health improvement programs which provide the framework within which all local NHS bodies will operate. Quality standards will be a key part in these local agreements.

Every NHS Trust is required to accept clinical governance to ensure quality. Clinical governance will ensure that:

- quality improvement processes (e.g. clinical audit) are in place and integrated with the quality programme for the organization as a whole;
- leadership skills are developed at the clinical team level;
- evidence based practice is in day-to-day use with the infrastructure to support it;
- good ideas, practices and innovations are systematically disseminated within and outside the organization;
- clinical risk reduction programmes are in place;
- adverse events are detected, openly investigated and the lessons learned promptly applied;

[4] *Ibid.,* s. 2.4.

- lessons for clinical practice are systematically learned from complaints made by patients;
- problems of poor clinical performance are recognized at an early stage and dealt with to prevent harm to patients;
- all professional development programmes reflect the principles of clinical governance;
- the quality of data collected to monitor clinical care is itself of a high standard.

At the national level the Department of Health and the NHS Executive are responsible for providing leadership and support to enable change. It will do this by:

- ensuring through the research and development program the provision and dissemination of high quality scientific evidence on the cost-effectiveness and quality of care;
- developing a programme of new evidence-based National Service Frameworks setting out patterns and levels of service which should be provided for patients with certain conditions;
- establishing the National Institute of Clinical Excellence to promote clinical- and cost-effectiveness by producing clinical guidelines and audits for dissemination through the NHS;
- establishing a Commission for Health Improvement to support and oversee the quality of clinical governance and of clinical services;
- working with the professions to strengthen the existing systems of professional self-regulation.

There are also a number of special health authorities that provide national services, for example the National Blood Authority and the NHS Direct (24 hour phone service staffed by nurses).

These reforms were first enacted in the *Health Act 1999* to amend the *National Health Service Act 1977*. Primary Care Trusts were established. Section 26 of the Act establishes the duty of Health Authorities, Special Health Authorities, Primary Care Trusts and NHS trusts to co-operate with each other in exercising their functions. Section 28 states that it is the duty of each health authority to prepare a plan that sets out a strategy for improving the health of the people for whom they are responsible and the provision of health care.

The Labour Government 2000s

The NHS plan was published by the Department of Health in 2000. It is a ten year plan setting out measures to introduce and encourage patient centered care and promising a 6.3 percent increase in funding over five years. The NHS plan promises:

- more power and information for patients;
- more hospitals and beds;
- more doctors and nurses;
- much shorter waiting times for hospital and doctor appointments;

- cleaner wards, better food and facilities in hospitals;
- improved care for older people;
- tougher standards for NHS organizations and better rewards for the best.

It sets out the core principles for the NHS:

- the NHS will provide a universal service for all based on clinical need, not ability to pay;
- the NHS will provide a comprehensive range of services;
- the NHS will shape its services around the needs and preferences of individual patients, their families and their carers;
- the NHS will respond to the needs of different populations;
- the NHS will work continuously to improve quality services and minimize errors;
- the NHS will support and value its staff;
- Public funds for healthcare will be devoted solely to NHS patients;
- the NHS will work together with others to ensure a seamless service for patients;
- the NHS will help keep people healthy and work to reduce health inequities.

Other initiatives are to include the creation of Care Trusts to commission health and social care to help patients falling in the crack between the NHS and social services. It also calls for the contracts for doctors to be modernized. It sets up a modernization agency to spread best practice and set national standards. NHS Trusts that perform well will be given more freedom and those that perform poorly will be subject to swift government intervention. There is a greater focus on patient involvement including the establishment of patient advocates for every hospital.

Shifting the Balance of Power was introduced in April 2001 by the Secretary of State for Health.[5] This initiative aims to place the needs of patients and staff at the heart of the NHS by giving greater authority and decision-making power to patients and front-line staff and changing organizational roles and relationships. Primary Care Trusts are given new powers and control over resources (74 percent of total NHS budget is allocated to these Trusts from 2004) to shape and commission services across the spectrum of hospital, community and primary services and from the range of providers in the public, private and voluntary services. NHS Trusts retain their current responsibilities but are accountable to Strategic Health Authorities (see below) and requiring Trusts to develop further patient and staff involvement and to engage in creating care partnerships with external partners. Strategic health authorities should be focused on delivery, committed to service quality and development, empowering of other actors, facilitative, developmental, involving and leading. The Department of Health will abolish its regional offices and create four Directors of Health and Social Care to support and develop the NHS, provide local contact and manage the strategic health authorities in terms of their performance. The Department will then focus on ensuring the development of national standards, securing resources and setting direction.

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[5] U.K., Department of Health, *Shifting the Balance of Power* (London: Department of Health, 2001) online: Department of Health <http://www.publications.doh.gov.uk/shiftingthebalance>.

The NHS Modernisation Agency was established to be the lead organization in reforming the NHS by redesigning services and supporting organizations throughout their changes. It was established in 2001, with its main aims being to modernize services and to develop leadership skills. The Modernisation Agency was superceded on 1st July 2005 by the NHS Institute for Innovation and Improvement**.** The Institute was established as a Special Health Authority. Its mission is to support the NHS and its workforce in accelerating the delivery of world-class health and healthcare for patients and public by encouraging innovation and developing capability at the frontline.

The NHS Institute will:

- work closely with clinicians, NHS organizations, patients, the public, academia and industry in the UK and world-wide to identify best practice;
- develop the NHS' capability for service transformation, technology and product innovation, leadership development and learning;
- support the rapid adoption and spread of new ideas by providing guidance on practical change ideas and ways to facilitate local, safe implementation;
- promote a culture of innovation and life long learning for all NHS staff.[6]

In 2002, the *National Health Service Reform and Health Care Professions Act* came into force. Health Authorities were renamed Strategic Health Authorities, but maintained similar functions as Health Authorities (developing strategy and performance-managing Primary Care Trusts and NHS Trusts to secure delivery and consistency of approach). Primary Care Trusts were given broader purchasing authority. The Act established Patient Fora for each NHS Trust and Primary Care Trust. Patient Fora:

- monitor and review the range and operation of services provided by, or under arrangements made by, the Trust for which it is established;
- obtain the views of patients and caregivers about the above and report to the Trust;
- provide advice and make reports and recommendations about matters relating to the range and operation of services;
- make available to patients and caregivers advice and information about services;
- promote the involvement of members of the public in consultations or processes leading to decisions or policies affecting people's health and monitor the success of patient involvement.

With regard to Primary Care Trusts, the Fora also:

- provide independent advocacy services to persons in the Trust's area;
- make available to patients and caregivers advice and information about the making of complaints;
- represent to any persons or bodies that exercise functions in the area of the Trust the views of members of the public.

[6] NHS Modernization Agency, "NHS Institute for Innovation and Improvement supersedes the NHS Modernisation Agency", online: NHS <http://www.wise.nhs.uk/cmsWISE/aboutUs/AboutMA.htm>.

Fora may also refer any relevant matter to the Commission for Patient and Public Involvement in Health. The Foras prepare annual reports that are submitted to the Trust, the Secretary of State, the Commission for Patient and Public Involvement in Health, the relevant Strategic Health Authority and any other relevant overview authority.

The Act also established the Commission for Patient and Public Involvement in Health. Its functions are to advise the Secretary of State about arrangements for public involvement in decision-making, the provision of advocacy services, the arrangement of Patients' Fora and other voluntary health organizations, and to provide staff to the Fora, to provide advice to the providers of independent advocacy services, and to set quality standards with regard to how the Fora exercise their functions or the advocacy services. It also promotes the involvement of members of the public in England in consultations or processes leading to decisions which may affect the health of the public. It reviews the annual reports of the Fora and makes recommendations to the Secretary of State about matters arising from those reports. It can also report concerns to any body it thinks appropriate (e.g., a regulatory body or the Commission for Health Improvement, now the Healthcare Commission). A recent report suggests that the Commission for Patient and Public Involvement in Health should be abolished but Patients' Fora should continue.[7] The Act also abolished Community Health Councils.

The *Health and Social Care (Community Health and Standards) Act 2003* establishes the Commission for Healthcare Audit and Inspection (Healthcare Commission) and abolishes the Commission for Healthcare Improvement and the National Care Standards Commission (see below). It also establishes NHS Foundation Trusts and sets up an independent regulator of NHS Foundation Trusts. NHS Foundation Trust status is awarded to NHS Trusts with an exemplary record for quality and performance. At this stage few Trusts have attained such status. NHS Foundation status means that the local community and staff run the Trust with considerably more autonomy than NHS Trust status accords. Accountability is to the independent regulator, which appraises performance based on the performance measurement assessments conducted by other agencies, and which has powers to intervene if a Trust is failing.

The *Health Protection Agency Act 2004* brings together in one agency the key elements in public health protection: emergency preparedness, biological, chemical and radiological expertise, within a regional, national and international framework.

Most recently, the government established the NHS Improvement Plan.[8] The Plan sets out the priorities for the NHS for the years 2004-2008. It establishes further priorities, including eliminating waiting times, increasing patient choice of providers, improving quality, and having patient safety as the central focus of health care. It also contains initiatives for those with long-term conditions. The Plan sets targets for improving the health of the population, including cutting health inequities by targeting people at greatest

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[7] U.K., Department of Health, *Reconfiguring the Department of Health's Arm's Length Bodies* (London; Department of Health, 2004) at 18 [*Reconfiguring*].

[8] U.K., Department of Health, *The NHS Improvement Plan: Putting People at the Heart of Public Services* (London: Department of Health, 2004).

risk, and reducing death rates for coronary heart disease, cancer, suicide and MRSA. It also discusses IT initiatives such as an electronic patient care records, an electronic booking service, and NHS Direct, NHS online and NHS Digital TV.

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.[9] Each country studied had different areas of good performance and weakness. The United Kingdom had low suicide rates, high polio vaccination rates and the incidence of pertussis was the lowest. There were virtually no financial barriers to medical care, diagnostic tests, or prescription drugs and the least difficulty in seeing a specialist. In contrast, cancer survival rates were lowest, measles incidence was highest. U.K. citizens reported the longest waits for elective surgery and U.K. physicians rated poorly on asking patients for their opinion, discussing the emotional burden of illness, and overall responsiveness.

The World Health Organization examined the relative performance of health systems of member countries.[10] 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 the United Kingdom ranked ninth on the list (Canada 7, Australia 12, U.S. 15, Denmark 20 and New Zealand 26).[11] The study also examined how efficiently health systems translate expenditure into health in regard to the overall achievement to expenditure. The United Kingdom ranked 18th in the world (Canada 30, Australia 32, Denmark 34, the U.S. 37, and New Zealand 41).[12] 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 choice of care provider). The U.K. ranked 26-27th (with Qatar) (the U.S. 1, Denmark 4, Canada 7-8, Australia 12-13, New Zealand 22-23). In terms of distribution of responsiveness (disadvantaged groups), the U.K. ranked 3-38 (third equal with 37 other countries including the U.S., New Zealand, Canada, Denmark and Australia).

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[9] Commonwealth Fund International Working Group on Quality Indicators, *First Report and Recommendations of the Commonwealth Fund's International Working Group on Quality Indicators: A Report to Health Ministers of Australia, Canada, New Zealand, the United Kingdom and the United States June 2004* (New York: Commonwealth Fund, 2004) online: <http://www.cmwf.org>.

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

[11] Because of statistical uncertainty, Canada, the U.K. and Australia are in the same range with less than 0.5 percent difference between them.

[12] Canada, Australia and Denmark are in the same range.

Patient Safety

The English healthcare system has experienced a number of major calamities in recent years. Two of the most noteworthy were the deaths of an inordinate number of children following cardiac surgery (Bristol)[13] and the murder by a physician of a large number of patients (Shipman).[14] These and other incidents have led to public inquiries, and have resulted in an acute level of awareness, concern, and politicized debate within both the media and the public. They have in turn given rise to a number of major patient safety and quality focused reforms in the past decade; thus, this report concentrates primarily on initiatives in England.

Key Statistics

Research indicates that up to 70,000 patients a year may die or be hurt in the NHS as a result or part result of a patient safety incident at an estimated cost of £2 billion per year.[15] More specifically, approximately 400 people die or are seriously injured in adverse events involving medical devices, nearly 10,000 people experience serious adverse events from drugs, around 1,150 people who have been in recent contact with mental health services commit suicide, nearly 28,000 complaints are made per year about aspects of clinical treatment in hospitals, the NHS pays out around £400 million a year in claims settlement, and hospital acquired infections (15 percent of which are thought to be preventable) cost nearly £1 billion.[16]

Policy Context

An Organisation with a Memory

In 2000, an expert group that had been charged with examining the processes for learning from adverse events in the NHS (chaired by the Chief Medical Officer) presented its report *An Organisation with a Memory*.[17] It reported that when things go wrong the most usual response is to find an individual(s) to blame. The focus of incident reports has tended to be the events immediately surrounding an adverse event. It notes that it is right

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[13] U.K., The Bristol Royal Infirmary Inquiry, *The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995: Learning from Bristol*, (Norwich: The Stationary Office Limited, 2001) online: The Bristol Inquiry <http://www.bristol-inquiry.org.uk/>.

[14] See for example, U.K., Department of Health, *Fifth Report - Safeguarding Patients: Lessons from the Past - Proposals for the Future* (Cm 6394) by the Shipman Inquiry (London: HMSO, 2004), online: The Shipman Inquiry <http://www.the-shipman-inquiry.org.uk/>.

[15] Charles Vincent, Graeme Neale & Maria Woloshynowych, "Adverse Events in British Hospitals: Preliminary Retrospective Record Review" (2001) 322:7285 BMJ 517.

[16] U.K., Department of Health, *An Organisation with a Memory: Report of an Expert Group on Learning from Adverse Events in the NHS Chaired by the Chief Medical Officer* (London: The Stationary Office, 2000) at vii-viii [*Memory*].

[17] *Ibid.*

that sometimes individuals must be held accountable for their actions, but that in most cases the causes of failures stretch beyond the acts or omissions of an individual. It notes that the culture in the NHS is one of blame and this is a barrier to active learning. Another barrier to active learning from error is an absence of reporting systems. The Report notes that some existing systems in the UK, such as the confidential inquiries system and the medical device incident reporting system, work very well, but that there are significant gaps in other areas. It recommended that the NHS develop:

- a unified mechanism for reporting and analysis when things go wrong;
- a more open culture in which errors or service failures can be reported and discussed;
- mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice;
- a wider appreciation of the value of the system approach in preventing, analyzing and learning from errors.

Specifically, it recommended that the NHS:

- develop a mandatory reporting scheme for adverse health care events and specified near misses;
- develop a scheme for confidential reporting by staff of adverse events and near misses;
- develop a reporting and questioning culture in the NHS;
- make better use of existing sources of information on adverse events;
- improve the quality and relevance of NHS adverse event investigations and inquiries;
- undertake a programme of basic research into adverse health care events in the NHS;
- make full use of new NHS information systems to help staff access learning for adverse health care events and near misses;
- act to ensure that important lessons are implemented quickly and consistently;
- identify and address specific categories of serious recurring adverse health care events (for example, the report recommends that by 2001 the NHS reduce to zero the number of patients dying or being paralysed by maladministered spinal injections, by 2005 reduce by 25 percent the number of incidences of negligent harm in the field of obstetrics and gynecology which result in litigation, by 2005 reduce by 40 percent the number of serious errors in the use of prescribed drugs, and by 2005 reduce to zero the number of suicides by mental health inpatients as a result of hanging from non-collapsible bed or shower curtain rails on wards).

The Department of Health responded to *An Organisation with a Memory* by issuing two reports: *Building a Safer NHS for Patients: Implementing an Organisation with a Memory*[18] and *A First Class Service: Quality in the New NHS*.

[18] U.K., Department of Health, *Building a Safer NHS for Patients: Implementing an Organisation with a Memory* (London: Department of Health, 2001).

Building a Safer NHS for Patients: Implementing an Organisation with a Memory

This report sets out the government's response to *An Organisation with a Memory* and the Government's plans for promoting patient safety. It proposes:

- establishing agreed definitions of adverse events and near misses for the purposes of logging and reporting them within the NHS;
- providing detailed guidance on the definitions for organizations, staff and patients;
- formalising a minimum dataset for adverse events and near misses;
- producing a standardized format for reporting;
- building expertise in root cause analysis;
- ensuring information from all existing adverse event reporting systems (medical devices, reactions to medications, Health and Safety Commissioner, Health and Safety) are fed into the new system;
- promoting a culture of reporting and patient safety within NHS organizations building on the transformation underway as a part of clinical governance;
- establishing a new independent body, the National Patient Safety Agency, to implement and operate the system to improve patient safety by reducing the risk of harm through error. It will collect and analyse information, assimilate other safety information, learns lessons and ensure that they are fed back into practice, service organization and delivery and produce solutions to identifiable risks to prevent harm, specify national goals and establish mechanisms to track progress (see further information below);
- developing only two ways of responding to a failure of a whole service, a seriously dysfunctional service or major systems weakness, namely an independent investigation commissioned by either the Department of Health or the Commission for Healthcare Improvement;
- reducing multiple investigations into the same event;
- integrating of mental health services inquiries;
- ensuring that the Department of Health only call a public inquiry if service failure results in serious harm to larger numbers of patients, where there is serious national concern, or where a major issue of ethics or policy is raised for the first time by an incident;
- providing that risks posed by the performance of an individual practitioner be dealt with by new procedures;
- ensuring that complaints be addressed under an NHS complaints procedure;
- reducing to zero the number of patients dying or being paralysed by the maladministration of spinal injections by the end of 2001;
- reducing by 25 percent the number of incidences of harm in the field of obstetrics and gynaecology which result in litigation by 2005;
- reducing by 40 percent the number of serious errors in the use of prescribed drugs by 2005;
- reducing to zero the number of suicides by mental health patients as a result of hanging from non-collapsible bed or shower curtain rails on wards by 2002;
- creating a research strategy for patient safety research.

In England, a Health Services Circular[19] has been issued explaining what could be considered a new procedure and what process a NHS Trust should follow if a clinician wishes to perform it.[20] The circular explains that medical practitioners wishing to undertake a new procedure that they have not used before or have only used outside the NHS (except in an emergency or when it is being used within a protocol approved by a Research Ethics Committee) must seek approval from the Trust's Clinical Governance Committee before doing so. If the procedure is the subject of NHS guidance, the Committee should consider whether the proposed use of the procedure complies with the guidance before approving it. If no National Institute of Clinical Excellence guidance is available, the Committee should only approve its use if:

- the doctor has met externally set standards of training;
- all patients are informed of the status of the procedure and the lack of experience in its use;
- the proposed arrangements for clinical audit are sound and will capture information on clinical outcomes that will be used to review continued use of the procedure;
- it has taken into account the Clinical Negligence Scheme for Trusts standard 5.2.6.

A First Class Service: Quality in the NHS

The second report issued by the government in response to *An Organisation with a Memory* is *A First Class Service: Quality in the NHS.*[21] The report notes unacceptable variations in quality throughout the NHS and attributes this to: the internal market where competition limits sharing; the lack of clear national standards of care; the lack of assessments as to which treatments are most effective; and the fact that the NHS is not sufficiently open and accountable about the quality of the service it offers to the public. It says that in the course of the next ten years, clear national standards will be set, but responsibility for delivery will be taken locally and backed by consistent monitoring arrangements. Devolution of responsibility will be matched with accountability for performance. National Standards will be set by National Service Frameworks and through the National Institute of Clinical Excellence (see below). National standards will be delivered through a new system of clinical governance, lifelong learning, and modernized professional self-regulation. Standards will be monitored by the Healthcare Commission, the National Framework for Assessing Performance, and an annual National Survey of Patient and User Experience of the NHS. The three national objectives are to:

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[19] A formal communication from the Minister primarily to NHS Chief Executives which usually contains a requirement for significant or urgent action. Many are 'quasi legislative' in nature.

[20] U.K., Department of Health, *Health Service Circular: The Interventional Procedures Programme, Working with the National Institute for Clinical Excellence to Promote Safe Clinical Innovation* HSC/011 (London: Department of Health, 2003).

[21] U.K., Department of Health, *A First Class Service: Quality in the New NHS* (London: Department of Health, 1998).

- improve continually the overall standards of clinical care;
- reduce unacceptable variations in clinical practice;
- ensure the best use of resources so that patients receive the greatest benefit.

The Report calls for the creation of the National Institute for Clinical Excellence (NICE) to promote clinical- and cost-effectiveness through guidance and audit. NICE is to produce national guidance and to assume responsibility for the funding and oversight of the confidential inquiries program, the National Prescribing Centre appraisals and bulletins, PRODIGY (a computer aided decision support system for GPs), the National Centre for Clinical Audit, the prescriber's journal, the Department of Health-funded National Guidelines Programme, Professional Audit Programme, and Effectiveness Bulletins.

The Report expands on the National Service Frameworks initiative discussed in *The New NHS: Modern, Dependable*. The frameworks:

- set national standards and define service models for specific services or care groups;
- put in place programmes to support implementation;
- establish performance measures against which progress within an agreed time scale will be measured.

The Report also expands on clinical governance, which is defined as "a framework though which NHS organizations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."[22] Chief Executives will be accountable on behalf of NHS Trust Boards for assuring the quality of NHS Trust Services and will provide Boards with regular reports on quality. Components of the framework include:

- a comprehensive framework of quality improvement activity (such as clinical audit) and processes for monitoring clinical care, including internal scrutiny supplemented by open and external review (full participation in audit programmes and confidential inquiries; evidence based practice is supported, ensuring the clinical standards of National Service Frameworks and National Institute of Clinical Excellence are implemented, workforce planning and development, continuing professional development, safeguards on patient information, effective monitoring of clinical care, processing for assuring the quality of clinical care);
- establishing clear policies aimed at managing risk, including those that support professional staff in identifying and tackling poor performance (controls assurance, clinical risk systematically assessed, critical incident reporting, complaints procedures, professional performance procedures, staff supported to report concerns);
- establishing clear lines of responsibility and accountability for the overall quality of clinical care (CEO has ultimate responsibility, designated senior clinician responsible for ensuring systems are in place and are effective, formal

[22] *Ibid.* at 3.3.

arrangements for Boards to discharge responsibility, regular reports to the Board, an annual report on clinical governance).

Primary Care Trusts have similar obligations.

All NHS employers had to have training and development plans for the majority of their health professional staff by the year 2000.

In regard to professional self-regulation, professional bodies must be openly accountable for the standards they set and the way they are enforced.

The report also calls for the establishment of a Commission for Health Improvement to provide independent scrutiny of local efforts to improve quality and to help address any serious problems. It is not to replace mainstream NHS performance assessment and management, but to complement and reinforce these processes. Its functions are to:

- provide national leadership to develop and disseminate clinical governance principles;
- independently scrutinize local clinical governance arrangements to support, promote and deliver high quality services through a rolling program of reviews;
- monitor national implementation of national service frameworks and review implementation of Frameworks and National Institute of Clinical Excellence guidance;
- help the NHS identify and tackle serious or persistent clinical problems;
- take responsibility for overseeing and assisting external incident inquiries.

The Report also discusses a national framework for assessing performance which will focus on health improvement, fair access to services, effective delivery of appropriate healthcare, efficiency, patient and care provider experience, and health outcomes of NHS care. It will be an integral part of NHS accountability arrangements and will underpin planning and management agreement between a health authority and its regional office, the NHS contribution to the Health Improvement Programme and the service agreement between a Primary Care Group and an NHS Trust.

National Institute for Health and Clinical Excellence

The National Institute for Clinical Excellence was established by statutory instrument in 1999 as a Special Health Authority.[23] Its purpose is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current 'best practice'. It aims to encourage faster uptake of new technologies, effective use of NHS resources, and equitable access to treatments of proven clinical and cost effectiveness.

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[23] *National Institute for Clinical Excellence (Establishment and Constitution) Order 1999* (U.K.), S.I./99-220; *National Institute for Clinical Excellence (Establishment and Constiution) Amendment Order 1999* (U.K.), S.I./99-2219.

It sets clear national guidelines for NHS services and treatments to improve the quality of healthcare across England and Wales. The National Institute for Clinical Excellence uses teams of experts to review health technologies and interventions, and to produce guidance, which is then disseminated. The Department of Health and the Welsh National Assembly are responsible for selecting the topics of focus. Currently, the National Institute for Clinical Excellence produces guidance in regard to clinical and cost effectiveness in three areas:

- technology appraisals - guidance on the use of new and existing medicines and treatments within the NHS in England and Wales (mandatory compliance in terms of funding);
- clinical guidelines - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales;
- interventional procedures - guidance on whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use in England, Wales and Scotland.

Once the National Institute for Clinical Excellence guidance is published, health professionals are expected to take it fully into account when exercising clinical judgment, but it does not override the individual responsibility of healthcare providers to make appropriate decisions according to the circumstances of the individual patient in consultation with the patient or his or her guardian or caregiver. Local health communities should review existing guidelines against National Institute for Clinical Excellence guidelines and respond accordingly. Since 2002, there is a statutory obligation falling on Trusts to provide funding for National Institute for Clinical Excellence approved technologies once a doctor has approved it for use by a patient (within three months, subject to extension by the Minister). Health authorities are expected to meet compliance costs from their budgets.

The National Institute for Clinical Excellence has a Board of Directors, executive and non-executive, a Partners' Council to review the annual report and act as a forum for the exchange of ideas, concepts and future plans (members are appointed by the Secretary of State and include patients and patient focused organizations, professional associations, and relevant healthcare industries), and a Citizens' Council. The Citizens' Council is comprised of thirty citizens from 'all walks of life' who bring forward the views of the public to the National Institute for Clinical Excellence decision-making about guidance for treatment and care in the NHS. It has no power to compel compliance with its recommendations or guidelines.

The focus on cost effectiveness leads some to suggest that the National Institute for Clinical Excellence is less a mechanism for quality and more a cost-control or rationing mechanism.[24] Recent research is suggesting that there may be a moderate link between National Institute for Clinical Excellence's technology guidance and uptake of new treatments but the link varies from treatment to treatment and region to region. The

[24] Mark Jones & Ben Irvine, "NICE or NASTY: Has NICE Eliminated the 'Postcode Lottery' in the NHS?", Civitas Health Briefing, (London: Civitas, 2003) at 27.

researchers note that new technologies are often heavily marketed and that whether the technology is provided or not depends on an assessment of the competing priorities of the Trust concerned.[25] There also appears to be anecdotal evidence that Trusts will not provide new treatments pending review by the National Institute for Clinical Excellence (10-14 month process) despite approval by other government agencies such as medicines authorities.[26] In one case, the Department of Health felt obliged to issue guidance that treatment can be provided in the interim and should not be withheld on cost grounds until the National Institute for Clinical Excellence had completed its appraisal. The research also notes that uptake of recommendations relating to fashionable treatment (e.g. obesity) was higher than that of unfashionable (e.g., Hepatitis C), and observed that as government sets the agenda for the National Institute for Clinical Excellence, unfashionable issues may not reach the National Institute for Clinical Excellence.[27] A British Medical Association survey in 2001 found that seven out of ten doctors believed that the National Institute for Clinical Excellence does not act independently, and seventy-four percent have disagreed with at least one of the National Institute for Clinical Excellence's decisions.[28]

A 2004 report suggests that the National Institute for Clinical Excellence should assume the responsibilities of the Health Development Agency to create a single excellence-in-practice organization covering both prevention and treatment of ill-health.[29] This occurred on 1 April 2005 and it became the National Institute for Health and Clinical Excellence (NICE). The National Institute for Health and Clinical Excellence will produce guidance in three areas of health:

- public health - guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector;
- health technologies - guidance on the use of new and existing medicines, treatments and procedures within the NHS;
- clinical practice - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.[30]

National Patient Safety Agency

The Safety Solutions and Clinical Programmes directorates of the National Patient Safety Agency (NPSA) develop national solutions that prevent incidents that adversely affect patient safety. The aim is to discover why things go wrong, to rectify incorrect actions, and to make it harder to do the wrong thing. Issues are also identified by the National

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[25] *Ibid.* at 14.
[26] *Ibid.* at 15.
[27] *Ibid.* at 20.
[28] *Ibid.* at 24.
[29] *Reconfiguring*, *supra* note 7.
[30] National Institute for Health and Clinical Excellence, "*About NICE Public Health*", online: <http://www.publichealth.nice.org.uk/page.aspx?o=about>.

Reporting and Learning System and from data produced by other organizations, both in the UK and abroad. Having identified an issue, the National Patient Safety Agency gathers further information from a variety of sources. Solutions are designed in partnership with clinical experts and patients. These are then piloted in NHS organisations to assess their impact. Risk assessments are conducted at every stage, to evaluate the effectiveness of the solutions and learn from the results. Key organisations, such as the Healthcare Commission are consulted throughout to ensure workability. These include hand hygiene campaigns and a package to reduce errors associated with the use of the drug methotrexate.

More general patient safety guidelines are also introduced by the National Patient Safety Agency, such as the *Seven Steps* Guide.[31] It recommends seven steps NHS organisations should take to improve patient safety. These are:

1. Build a safety culture;
2. Lead and support staff;
3. Integrate risk management activity;
4. Promote reporting;
5. Involve and communicate with patients and the public;
6. Learn and share safety lessons;
7. Implement solutions to prevent harm.

Guidelines for talking to patients and relatives following a serious patient safety incident are being formulated by the National Patient Safety Agency.

There were a number of other stand-alone entities in the NHS that were concerned with aspects of patient safety. As a result of a re-organisation in 2005 many of these entities are now under the general stewardship of the NPSA. These include: NHS Estates, the National Clinical Assessment Authority (now Service), and the Confidential Inquiries. A 2005 report recommended that most of the functions of NHS Estates, especially those relating to standard setting and quality design, be subsumed within the National Patient Safety Agency to enable the NPSA to "deepen its focus on safety and improving the patient experience."[32] The safety related responsibilities of NHS Estates includes setting clear national standards for stewardship of NHS estates, procurement, construction, engineering, design quality, and hospitality services. NHS Estates manages a large research and development budget, and recently completed projects include Lighting and Colour Design for Hospitals and Reduction of Hospital Acquired Infections by Design. It produces a number of standards, including *Standards of Cleanliness in the NHS*, which aims to reduce hospital-acquired infection by modernising the disinfection and sterilisation of surgical instruments, identifying risks within the existing systems and building innovative solutions. Work is being undertaken to convert wards to single-sex and to design dormitory style wards to increase privacy, dignity and comfort.

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[31] National Patient Safety Agency, *Seven Steps to Patient Safety: An Overview Guide for NHS Staff* (London: National Patient Safety Agency, 2004).
[32] *Reconfiguring, supra* note 7 at 17.

In 2005, the National Audit Office published a report of a review of patient safety initiatives in the health system.[33] It concludes that overall NHS Trusts have developed open and fair report culture although pockets of blame remain and there is still significant scope to improve performance. It states that this has been achieved through the use of clinical governance frameworks, effective risk management systems and the use of reporting systems. At a national level, implementation of the National Reporting and Learning System has been slow and there is a need to improve evaluation and sharing of lessons and solutions across the sector. However, there is no clear system to monitor whether Trusts are learning lessons and changing practice where appropriate. It makes a number of recommendations about how the patient safety framework can continue to improve.

Institutional Regulation

There is a wealth of legislation relating to the licensing and regulation of institutional providers of health services.

Standards: NHS Institutions

Section 46 of the *Health and Social Care (Community Health and Standards) Act 2003* states that the Secretary of State may prepare and publish statements of standards in relation to the provision of health care by and for English NHS bodies and cross-border Special Health Authorities. The standards are to be "taken into account" by every NHS body and cross-border special health authority when discharging its duty under section 45. The Act also makes provision for the Welsh Assembly to set standards for Wales NHS bodies.[34]

The Healthcare Commission (Commission for Healthcare Audit and Inspection) is the agency charged with overseeing institutions and administering the statutes and regulations that regulate them. It was established by the *Health and Social Care (Community Health and Standards) Act 2003* as an executive non-departmental public body and commenced operations in 2004. It takes over the work of the Commission for Healthcare Improvement (formed 1999 and abolished 2004) as well as the private and voluntary health care functions of the National Care Standards Commission (abolished 2004) and covers the elements of the Audit Commission's work which relate to the efficiency, effectiveness and economy of healthcare.[35] Following the recommendations

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[33] U.K., National Audit Office, *A Safer Place for Patients: Learning to Improve Patient Safety* (London: National Audit Office, 2005).

[34] *Health and Social Care (Community Health and Standards) Act 2003*, (U.K.), 2003, c.43, s. 47 [*HSCA*].

[35] The government and others involved in the health sector became concerned that the sector was being overregulated with a plethora of regulatory agencies with sometimes overlapping responsibilities which were poorly coordinated, bureaucratic and whose operations placed to great a burden on front-line health providers. In 2003, the Minister of Health announced that the Health Select Committee would review the aims and functions of 'arms length' regulatory agencies in the health sector. In 2004, a report entitled *Reconfiguring the Department of Health's Arm's Length Bodies*, *supra* note 7, recommended that many of

of a recent report, it may also in the future assume responsibility for the functions currently performed by the Mental Health Act Commission.[36] In relation to the NHS, the Healthcare Commission's general function is to encourage improvement in the provision of healthcare by and for NHS bodies.[37] Its specific functions are to:

- independently assess the performance of the health services from patients' perspectives using standards set by the Department of Health;
- coordinate NHS inspections with a range of other organizations in order to minimize disruption to healthcare staff;
- identify how effectively public funds are used within healthcare, particularly whether tax payers are getting good value for money;
- develop an independent second stage for complaints about the NHS which cannot be resolved locally;
- investigate serious failures in healthcare services;
- publish regular ratings of NHS hospitals and trusts, and an annual report on healthcare in England and Wales.

The Department of Health sets national standards through the national service frameworks. An external reference group brings together professionals, service users and carers, health service managers, and partner agencies. The process is managed by the Department of Health. The frameworks set standards and create strategies to support the development and improvement of services in these areas. Established frameworks are for:

- Cancer
- Paediatric intensive care
- Mental health
- Coronary Disease
- Older People
- Diabetes

In preparation are frameworks for:

- Renal services
- Children's services
- Long term conditions

The Department of Health has also recently published a report entitled *National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005/06-2007/08.* This reduces the number of national targets from 62 to 30. Existing national targets will become core standards. Standards are defined in the document as: "…a means of describing the level of quality that health care organisations are expected to meet or aspire to. The performance of organizations can be assessed against this level

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these 'arms length' agencies are to be merged to streamline their functions and to save significant amounts of money.

[36] *Reconfiguring, supra* note 7 at 12, but this has not yet occurred.

[37] *HSCA, supra* note 34 , s. 48.

of quality."[38] Health care organisations must comply with core standards. The Healthcare Commission will assess compliance and progress towards obtaining developmental standards which aim to encourage developmental progress (National Service Frameworks and National Institute of Clinical Excellence guidance are part of the developmental standards).

The Core Standards outcomes include:

1) Patient Safety is enhanced by the use of health care processes, working practices and systemic activities that prevent or reduce the risk of harm to the patient;
2) Patients achieve health care benefits that meet their individual needs through health care decisions and services based on what assessed research evidence has shown provides effective clinical outcomes;
3) Managerial and clinical leadership and accountability, as well as the organisation's culture, systems and working practices, ensure that probity, quality assurance, quality improvement and patient safety are central components of all the activities of the health care organization;
4) Health care is provided in partnership with patients, their carers, and relatives respecting their diverse needs, preferences and choices, and in partnership with other organisations (especially social care organisations) whose services impact on patient well-being;
5) Patients receive services as promptly as possible, have choice in access to services and treatments, and do not experience unnecessary delay at any stage of service delivery or of the care pathway;
6) Care is provided in environments that promote patient and staff well-being and respect for patients' needs and preferences in that they are designed for the effective and safe delivery of treatment, care or a specific function, provide as much privacy as possible, are well maintained, and are cleaned to optimize health outcomes for patients;
7) Programmes and services are designed and delivered in collaboration with all relevant organisations and communities to promote, protect and improve the health of the population served, and to reduce health inequalities between different population groups and areas.

The Health Care Standards Unit and Controls Assurance Support Unit are based at Keele University. The HCSU has responsibilities for maintaining and evaluating health and social care standards in a national and international context. It works with the Department of Health, the Healthcare Commission, and other bodies to support the implementation of the standards, and to ensure that the standards are relevant and accurate. The Controls Assurance Support Unit is also at the University of Keele, and facilitates the maintenance of existing controls assurance standards, promotes benchmarking, and evaluates the effect of the Controls Assurance Program.[39]

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[38] U.K., Department of Health, *National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005/06-2007/08* (London: Department of Health, 2004) at 22.
[39] See Health Care Standards Unit, online: <http://www.hcsu.org.uk>.

Standards: The Private and Voluntary Sector

The Commission's duty to regulate the private and voluntary sector is laid out in the *Health and Social Care (Community Health and Standards) Act 2003*. Details of regulation are in the *Care Standards Act 2000* and the *Private and Voluntary Healthcare (England) Regulations 2001*. In addition the Commission is responsible for encouraging improvement in the quality of care services across England, reporting to government on the provision and quality of registered services across England, advising the government of changes to the National Minimum Standards, and providing better and more accessible information about independent and private healthcare to the public.

Section 23(1) of the *Care Standards Act 2000* authorises the appropriate Minister to prepare and publish statements of national minimum standards applicable to independent hospitals, independent clinics and independent medical agencies. In 2002 the Department of Health created the *Independent Health Care National Minimum Standards Regulations*.[40] These set out core standards for information provision, quality of treatment and care, management and personnel, complaints management, premises, facilities and equipment, risk management procedures, records and information management and research. They contain service-specific standards for acute hospitals, mental health establishments, hospices, maternity hospitals, termination of pregnancy establishments, prescribed techniques and technologies and private doctors.

A Private and Voluntary Healthcare provider is required to be registered with the Healthcare Commission if they intend to operate the following types of establishments:

- private acute and mental health hospitals as defined in section 2(3)(a) & (b) of the *Care Standards Act 2000*;
- independent clinics where services are provided by medical practitioners as defined under section 2(4) of the *Care Standards Act 2000*.

If an establishment provides the following listed services they must register with the Commission:[41]

- medical treatment under anesthesia or sedation;
- dental treatment under general anesthesia;
- obstetric service and, in connection with childbirth, medical services;
- termination of pregnancies;
- cosmetic surgery;
- treatment using prescribed techniques and technologies (e.g. laser and intense pulse light therapy, hyperbaric oxygen chambers, private dialysis, IVF and endoscopy);
- overnight treatment or nursing services for persons liable to be detained under the *Mental Health Act 1983.*

[40] U.K., Department of Health, *Independent Health Care National Minimum Standards Regulations* (London: the Stationary Office, 2002).
[41] *Private and Voluntary Healthcare (England) Regulations 2001* (U.K.), S.I. 2001/3968, s.3.

The institutions are required to publish a patients' guide. The institutions are also required to prepare and implement policies and procedures in relation to:[42]

- the arrangements for admission or acceptance of patients, their transfer to hospital where required and discharge;
- the arrangements for assessment, diagnosis and treatment of patients;
- ensuring that the premises used by or for the purposes of an establishment are fit for the purpose for which they are used;
- monitoring the quality and suitability of facilities and equipment;
- identifying, assessing and managing risks to employees, patients and visitors;
- the creation, management, handling and storage of records and other information;
- the provision of information to patients and others;
- the recruitment, induction and retention of employees and their employment conditions;
- the granting to and withdrawal of practicing privileges for medical practitioners;
- ensuring that research conducted is carried out with the consent of any patient or patients, is appropriate for the establishment concerned, and is in accordance with up-to-date and authoritative published guidance on the conduct of research projects;
- informed consent, and assessment of patients' competence to consent to treatment.

There is a duty to provide services that meet the individual's needs, reflect best practice, and use appropriate equipment (suitable for the purposes, properly maintained, and in good working order). Additional responsibilities include ensuring appropriate sterilization and disinfection of reusable medical devices, making suitable arrangements for the ordering, recording, handling, safe-keeping, safe administration and disposal of medicines, and minimizing the risk of infection, toxic conditions, and the spread of infection. Food must be provided in adequate quantities at appropriate quantities and intervals, properly prepared, wholesome, nutritious, and suitable. There is also a requirement to introduce and maintain a system for reviewing the quality of treatment. The registered person must ensure that there are at all times an appropriate number of suitably qualified, skilled and experienced persons employed. The registered person must also ensure that employees receive appropriate training, supervision and appraisal, can seek further qualifications, and are provided with a job description outlining responsibilities. There is a duty to take steps to address any aspect of a person's clinical performance or non-clinical performance. Every employee or medical practitioner granted privileges must be fit for the purposes of the establishment. There is an obligation to keep various types of records. The registered person must also establish a complaints procedure. The premises must be in a location and of a physical design and layout that allow it to achieve its ends. The registered persons shall ensure that the premises or rooms are: of sound construction; kept in a good state of repair; of a size and layout suitable for the purposes; appropriately equipped and furnished; clean; meet appropriate standards of hygiene; free from hazards to their safety; and, if surgical procedures are undertaken, life-support available; and the electrical supply must be secured. There are

[42] *Ibid.,* s. 9.

also requirements to secure the facility against the risk of fire. There are also a number of other procedural requirements. There are additional requirements for independent hospitals.

The facility is required to report to the Healthcare Commission the death of a patient, any serious injury to a patient, the outbreak of any infectious disease, and any allegation of misconduct resulting in actual or potential harm to a patient.

Funding and Accountability Mechanisms

It appears that financial incentives are a minor factor in the U.K. to encourage quality and safety. Quality and safety are attained through regulatory means and publication of audit results. As more autonomy is devolved to Foundation Trusts, there is even less resort to financial incentives. This is because in order to gain and retain a high status, national standards for quality and safety must be complied with.

Under section 45(1) of the *Health and Social Care (Community Health and Standards) Act 2003*: "It is the duty of each NHS body to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care provided by and for that body." This was a continuation of a provision placed into the *Health Act 1999* which states "It is the duty of each Health Authority, Primary Care Trust and NHS Trust to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care which it provides for individuals."[43]

Monitoring Mechanisms

There is an NHS performance ratings system for NHS Trusts. The system is administered by the Healthcare Commission and awards stars for levels of performance, with three stars indicating high levels and zero stars showing the poorest performing Trusts. Performance of the Trusts is assessed against key targets and performance indicators. Key targets reflect the minimum standards that all are expected to achieve and map onto the Planning & Priorities Framework priorities. The nine key targets are:

- 12 hour wait for emergency admission from Accident and Emergency (A&E) after the decision is made to admit;
- two week wait for all cancer treatment;
- financial management;
- hospital cleanliness;
- improving working lives;
- outpatient and elective booking;
- outpatients' waiting time no longer than the standard;
- no patients waiting longer than the standard for admission for elective surgery;
- total time in A&E four hours or less.

[43] *Health Act 1999* (U.K.), 1999, c. 8, s. 18(1).

Other indicators (35 in total) are used to ensure a balanced scorecard, and include: clinical factors such as death rates, emergency readmissions, and infection control; patient service factors such as food standards, cancelled operations, and complaints; and capacity factors such as junior doctors' hours and staff opinion surveys. Reports are issued to each Trust and are published on the Healthcare Commission's web-site. They tend to be widely discussed in the media. The star rating system attracts strong criticism from the health sector. Critics complain that the star system: does not reflect patients' interests; ignores or distorts clinical priorities; turns managers into robots focusing entirely on meeting targets; reduces the performance of complex organisations into a crude four point scale; penalizes Trusts and undermines staff morale when often the Trust can do little to change things (e.g., because of budget deficits, aging buildings, etc.)[44] However, Sir Ian Kennedy suggests there is some evidence that targets have contributed to improvements in care and in areas such as waiting times where people desire improvement. Indeed, the Healthcare Commission suggests that Trusts are improving their general performance against tougher targets (with the exception of financial performance).[45] However, the Healthcare Commission is now ceasing to use the star system and has implemented a new system where it rates Trusts by reference to an annual health check which aims to give a more comprehensive picture of NHS performance.

Information from internally conducted clinical governance reviews is also used in determining organizational performance. A clinical governance review assesses:

- Risk management;
- Clinical audit;
- Clinical effectiveness;
- Patient/service user, carer, and public involvement;
- Use of information;
- Staffing and staff management;
- Education and training and continuing personal and professional development.

After each review, an action plan to address areas identified by the report for improvement is prepared by the Trust, approved by the Healthcare Commission and published.

Working Conditions Regulation

The Council of the European Union passed the *European Working Time Directive,*[46] which lays down minimum requirements in relation to working hours, rest periods,

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[44] Sir Ian Kennedy, "Think Tank" *The Guardian* (21 July 2004) 11.

[45] Healthcare Commission, News Release, "Star Ratings How NHS Improving Against Tougher Targets" (27 July 2005), online: HC <http://www.healthcarecommission.org.uk/NewsAndEvents/PressReleases/PressReleaseDetail/fs/en?CONTENT_ID=4018735&chk=kAV%2BG2>.

[46] EC, *Council Directive 93/104 of 23 November 1993 concerning certain aspects of the organization of working time,* [1993] O.J. L. 307/18 at 1.

annual leave and working arrangements for night workers who are employees. The directive was enacted into U.K. law as the *Working Time Regulations* in 1998.[47] Those to whom the regulation applies shall not exceed an average working time per week of 48 hours unless there is a written agreement that the employee will work longer hours. A night worker's hours of work are not to exceed eight hours per day if his or her work involves heavy physical or mental strain (as identified in a collective or workforce agreement or risk assessment) and a night worker performing normal tasks shall not exceed an average of eight hours for each 24 hour period. Each worker is entitled to a rest period of eleven consecutive hours in each 24 hours but it may be interrupted in the case of activities involving periods of work that are split up during the day or are of short duration. Each employee is entitled to a weekly uninterrupted rest period of 24 hours or 48 in each 14 day period. If an employee works over six hours, he or she is entitled to a rest break. These requirements previously did not apply to doctors in training. Further, the parts of the regulation that relate to night work, rest periods, and rest breaks do not apply in relation to a worker "where the worker's activities involve the need for continuity of service or production, as may be the case in relation to – (i) services relating to the reception, treatment or care provided by hospitals or similar establishments, residential institutions and prisons".[48]

From August 2004 the regulations are extended to include doctors in training. It is being phased in, with a maximum hours worked requirement reducing from 58 hours in August 2004 to 48 hours by 2009.[49]

Professional Regulation

Regulation of health professionals in the United Kingdom is carried out through a process of self-regulation, although some argue that it is increasingly moving away from pure conceptions of self-regulation to professional regulation.[50] In the past, the core tasks of the self-regulated health professions were to register qualified professionals and to erase from the register those found to have committed serious breaches of the professional code of conduct.[51] Now the focus has shifted to the following:

- ensuring safe practice and protecting patients;
- ensuring continuing competence in practice;
- candor and honesty on the part of professionals;
- partnership in the relationship between the client/professional;
- respect for diversity in registering professionals;
- teamwork;

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[47] *The Working Time Regulations 1998* (U.K.), SI. 1998/1833.
[48] *Ibid.*, s. 21(c)(i).
[49] *The Working Time (Amendment) Regulations 2003* (U.K.), S.I. 2003/1684.
[50] Robert Kaye, "Professionals, Politicians and the Strange Death of Self-Regulation" (2003) Risk & Regulation 7.
[51] Judith Allsop *et al, Regulation of the Health Professions: A Scoping Exercise Carried out on Behalf of CRHP Final Report* (Leicester: Health Policy Research Unit, 2004) at 12.

- flexibility in the tasks associated with the particular professions;
- shared education programmes;
- some professional taking the lead in supervising other health professionals;
- use of evidence based practice;
- learning through the period of professional service;
- informing the public about the professional services available so that they can make a choice;
- informing and involving the public so that they can act as partners in the task of regulation.[52]

There are nine health profession regulation councils in the U.K., although one regulates 14 separate health professions. Each has its own legislation setting out its functions. Since 1999 legislation may now be amended by Her Majesty by Order in Council.[53] Rules made by the majority of the health professional regulatory authorities do not come into force until approved by order of the Privy Council. All regulatory bodies have substantial lay representation on the governing boards. The need for appropriate and properly used channels for consulting with members and the public has been identified as an issue by the Better Regulation Task force, as consultation is seen as essential to the proper accountability of self-regulatory agencies. Some bodies are required by legislation to consult when making rules.

The purpose of the General Medical Council (GMC), for example, is to protect, promote, and maintain the health and safety of the public by maintaining an up-to-date register of qualified doctors, setting the standards of good medical practice, setting and promoting high standards of medical education, and dealing firmly and fairly with doctors whose fitness to practice is in doubt. The GMC, unlike any of the other bodies, also has a statutory power to provide advice to members of the medical profession on the standards of professional conduct, standards of professional performance, and medical ethics. In response to concerns expressed in the Bristol and some other reports, the GMC has implemented reforms in the registration and licensing of doctors (to begin 2005). Doctors must qualify for registration. However, registration alone will not qualify a doctor to practice - a license is also required. There will be a periodic (5 year) revalidation when a doctor is required to demonstrate that he or she remains fit to practice. The license will define the doctor's scope of practice and signify that he or she is fit to work.

Continuing professional development (CPD) is mandatory for many professions in the U.K. For example, the Act establishing the Chiropractic Council provides for the making of statutory rules for mandatory CPD. There are three basic models:

- a practitioner is required to undertake a certain number of hours of CPD and it is left to the discretion of the practitioner to decide on their own needs;

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[52] *Ibid*.

[53] Amendments can be made pursuant to the authority contained within s.60 *Health Act 1999*, *supra* note 43.

- the Council suggests hours and options and monitors compliance of all registrants through spot checks, and failure to undertake CPD may lead to disciplinary action;
- fitness to practice is periodically reassessed.

The Councils determine whether a registrant continues to be fit to practice. Councils review fitness on the following grounds[54]:

- criminal conviction (thus, criminal process is adhered to first);
- ill-health;
- professional misconduct;
- determination by another regulator that the registrant is unfit to practice.[55]

The Councils establish standards and guidelines for the practice of each profession. All Councils have general Codes or sets of standards which contain the core values of the particular profession. There is now more emphasis on safe practice and on the duty to report poor practice by colleagues than in the past.[56] For example, the General Medical Council has set clear guidelines on what constitutes "good medical practice."[57] The GMC Annual Review (2002) describes these guidelines as follows: *"Good Medical Practice* … is a working document, not a philosophical treatise or an account of an unrealizable ideal. It establishes standards which doctors can and should meet, and makes clear that a failure to do so, if persistent or serious, will put doctors' right to continued registration at risk."[58] Some professional bodies also have competency statements which outline the areas of skill or knowledge required to practice.

Some central agencies also play a role in health professional regulation. The National Clinical Assessment Authority was established in 2001[59] as a special health authority set up by statutory instrument.[60] After a review it is now is one of the entities that operates under the stewardship of the NPSA. [61] It is now known as the National Clinical Assessment Service (NCAS). Its purpose is to provide a support service to health authorities, primary care trusts, hospitals and community trusts that are faced with concerns about the performance of an individual doctor or dentist. It takes referrals, provides advice, and carries out targeted assessments where necessary, and offers an educational and mediated objective solution.

Once a referral is received, NCAS offers advice and support towards obtaining local resolution. The assessment process focuses on occupational health, behavioural and

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[54] In case of a claim of malpractice, review is postponed until the court decision is rendered, and the results are considered by the relevant Council.
[55] Decisions are placed on the website of the relevant regulator.
[56] Allsop *et al*., *supra* note 51 at 67.
[57] General Medical Council, *Duties of a Doctor: Good Medical Practice* (London: General Medical Council, 1998).
[58] Allsop *et al*. *supra* note 51 at 66.
[59] National Clinical Assessment Authority, online: <http://www.ncaa.nhs.uk>.
[60] *National Clinical Assessment Authority (Establishment and Constitution) Order 2000* (U.K.), S.I./00-2961.
[61] *Reconfiguring, supra* note 7 at 17.

clinical performance. It is chaired by a lay assessor in order to ensure impartiality, and other assessors mirror the specialty of the doctor/dentist being assessed. An assessment report produces recommendations that identify actions and educational or organizational support required. NCAS has memoranda of understanding with the General Medical Council, and the Healthcare Commission. It also works closely with other groups such as the Royal Colleges, doctor representatives, patient representatives and other stakeholders. It tries to keep doctors in their positions wherever possible. A survey suggests that NHS consultants and managers view this as a positive step and think there is a role for the NCAS in helping Trusts develop and strengthen performance procedures.[62]

In November 2003, the National Audit Office released a report on the management of clinical staff, which found that between April 2001 and July 2002, over 1000 full-time clinicians were suspended on full pay at a cost of £29 million. The Audit Office identified a number of occasions wherein clinicians were suspended despite evidence of systemic failures rather than individual shortcomings. The National Patient Safety Agency designed an Incident Decision Tree designed for NHS managers. The Tree prompts managers with questions to help them take a systematic, transparent, and fair approach to decision-making around suspensions. It helps to decide whether staff should be suspended from duty, to explore alternatives to suspension such as temporarily relocating staff or changing their duties, and to consider other actions as the investigation progresses. NPSA Joint Chief Executive Susan Williams said:

> All too often in the past the immediate response to an error in the NHS has been to blame the member of staff involved and to ignore the underlying causes. The evidence tells us that often when things go wrong the causes can be traced back to systems. An automatic decision to blame and suspend staff makes it more likely that errors will be covered up and that the right lessons will not be learned.[63]

Regulating the Regulators

The Council for the Regulation of Health Professionals is another agency that plays a role in health professional regulation.[64] It can be said to regulate the regulators. Its general functions are to:

- promote the interests of patients and other members of the public in relation to the performance of the regulatory bodies for the health professions and their committees and officers;
- formulate best practice in the performance of the functions of the regulatory bodies;

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[62] National Clinical Assessment Authority, Press Release,"NCAA making a difference" (19 September 2003).

[63] National Patient Safety Agency, Media Release, "NPSA Launches Decision Making Tool to reduce Unnecessary Suspensions and Support a Safety Culture" (5 May 2004).

[64] It was established pursuant to section 25 of the *National Health Service Reform and Health Care Professions Act 2002* (U.K.), 2002, c. 17.

- formulate principles relating to good professional self-regulation and encourage conformity by regulatory bodies;
- promote co-operation between regulatory bodies and between regulatory bodies and other bodies performing corresponding functions.

It may investigate and report on the performance by each regulatory body of its functions, compare the performance of two bodies with corresponding functions, and make recommendations to a regulatory body to change the way in which it performs its functions. If the Council considers it desirable for the protection of members of the public, it may give directions requiring a regulatory body to make rules in order to achieve an effect specified in the regulations. These directions must be approved by the Privy Council.[65] The Secretary of State may also make regulations about the investigation of complaints made to the Council about the manner in which any professional regulatory body exercised its functions.[66]

Lastly, and very significantly, the Council receives copies of all disciplinary decisions and settlement agreements of the professional regulatory bodies under its purview, and may refer to court the decision of a regulatory body in relation to professional discipline that it considers unduly lenient or which in its view should not have been made.[67] This section was inserted to allow the Council to refer a case to a court "where there has been a perverse decision or the public interest has not been fully or properly served"[68] and "where the public interest in having a clearly perverse decision reviewed by a Court outweighs the public interest in the independent operation of self-regulation …"[69] Approximately twelve cases per year are referred to court. Interestingly, these appeals go before the administrative branch of the court, and are heard by one of two specialized judges. In case of a finding that the disciplinary panel has rendered a wrong decision or was overly lenient, the judge may step into the shoes of the disciplinary panel or, in the primary route followed, may send the case back to the panel for re-assessment of the appropriate discipline.

The court has confirmed that the Council may also bring 'not guilty' verdicts to the court,[70] but has indicated that the powers of the court to overturn a decision based upon its being too lenient are limited by the term "unduly".[71]

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[65] *Ibid*,, s, 27.
[66] *Ibid*., s. 28.
[67] *Ibid*., s. 29.
[68] United Kingdom, House of Commons Standing Committee A, *Hansard*, (13 December 2001) at cols. 424-427 (Hon. John Hutton).
[69] The note on the relevant clause of the Bill.
[70] Council for the Regulation of Healthcare Professionals, Media Release, "Council for the Regulation of Healthcare Professionals Welcomes High Court Ruling on New Powers" (29 March 2004).
[71] Council for the Regulation of Healthcare Professionals, Media Release, "Independent Body Brings Appeal Under New powers to Protect the Interests of the Public" (31 March 2004).

Products Regulation

There are a number of bodies involved in the regulation of products, although a recent merger of the two most significant agencies has reduced this number. The Medicines Control Agency and the Medical Devices Agency recently merged to become the Medicines and Healthcare Products Regulatory Agency which intends to ensure that all medicines, medical devices and equipment meet appropriate standards of safety, quality and performance. The key activities are:

- regulating medical devices;
- licensing of medicines before marketing and subsequent variations;
- regulation of clinical trials;
- operating adverse incident reporting system for medical devices;
- issuing safety warnings;
- responsibility for reporting, assessment and communications of defective medicines;
- monitoring of medicines and acting on safety concerns after marketing;
- ensuring compliance to standards of pharmaceutical manufacture and wholesaling;
- enforcement of requirements;
- evaluating medical devices to inform purchasing and encourage safe use;
- managing the General Practice Research Database (GPRD);
- setting quality standards for drug substances through the "British Pharmacopoeia";
- providing advice and guidance on medicines and medical devices.

The Agency administers a voluntary ‘yellow-card’ system for the reporting of suspected adverse drug reactions. The system has been operational since 1964 and more than 400,000 cards have been submitted by health providers and, as required by statute, drug companies (reforms are occurring to allow patients to report). Reports are entered into a database. The Pharmacovigilance Group of the Post-Licensing Division use the data from the database to assess the causal relationship between the drugs and reported reactions, and to identify possible risk factors contributing to the occurrence of reactions, for example, age or underlying disease. As a result, dosage may be changed, special warnings attached or, rarely, drugs may be withdrawn from the market. A similar voluntary system operates for medical devices. Information is entered into a database but in the event of death or serious injury, an immediate investigation may be undertaken by the agency. In other cases, the investigation will most likely be led by the manufacturer and monitored by the agency.

The agency also has a standards setting function. For example, it created the *Medical (Equipment and Devices) Controls Assurance Standard* which requires Trusts, amongst other things, to report and record incidents, and to quarantine equipment, until an investigation can be completed.

The National Patient Safety Agency aims to develop sustainable national solutions that address safety issues. It works with industry, in particular drug and device manufacturers, to instigate change, and to research the use of new technologies to improve patient safety. For example, it is investigating the use of new technologies such as bar-coding, radiofrequency, and fingerprinting to ensure that patients get the correct treatment. It is working with the NHS Purchasing and Supply Agency and infusion device manufacturers to implement practical solutions to reduce errors associated with infusion therapy. It is collaborating with prescribing and dispensing system software suppliers to develop systems to prevent misprescription of methotrexate in the wrong dose or frequency, and to remind providers of the need for regular monitoring. It is also working with the pharmaceutical industry to change the visual presentation of tablets, the instructions, and the container design.

National Institute of Clinical Excellence has some limited role in assessing the clinical and cost effectiveness of pharmaceuticals and medical devices.

The fourth report of the Shipman Inquiry recommended a tighter system of regulating controlled drugs. Dr Shipman is alleged to have killed large numbers of his patients through injecting them with diamorphine, which he was able to access because of his profession. It recommends the creation of a national inspectorate of controlled drugs to crack down on the misuse of prescription drugs by doctors. The inspectorate would be nationally coordinated but regionally based, and its responsibilities would include disposing of surplus controlled drugs after a patient's death. The Inquiry recommended restrictions on doctors prescribing controlled drugs for their own use or for the use of their immediate family, prescribing outside the requirements of their normal clinical practice and prescribing if they have convictions for controlled drug offences. The Report proposes greater regulation of the handling and safekeeping of controlled drugs from the supplier to the patient's home. It recommends that doctors provide a complete audit trail to account for the movement of controlled drugs in a manner that does not interfere with patient care.[72]

Inquiry Processes

There have been a number of recent public inquiries into primarily safety-related events that have occurred in the National Health Service in England. In fact there have been 59 inquiries between 1974 to 2002, 52 from 1990 onwards.[73] Notable are: The Bristol Inquiry;[74] the Shipman Inquiry;[75] the Royal Liverpool Inquiry;[76] the Rodney Ledward

[72] Clare Dyer, "Shipman Inquiry Recommends Tighter Rules on Controlled Drugs" (2004) 329:7459 B.M.J 188.
[73] Kieran Walshe & Joan Higgins, "The Use and Impact of Inquiries in the NHS" (2002) 325:7369 B.M.J. 895.
[74] Deaths of children undergoing pediatric cardiac surgery. Online: The Bristol Inquiry <http://www.bristol-inquiry.org.uk/>.

Inquiry;[77] and the Richard Neale, William Kerr, Michael Haslam and Clifford Ayling Inquiries (not public).[78] Significant reforms were initiated as the result of these inquiries.

Inquiries in the NHS range from small internal inquiries to statutory inquiries set up by parliament. Inquiries investigate allegations of poor clinical performance, major service failure, or criminal misconduct.[79] Inquiries can be established by the Secretary of State under section 84 of the *National Health Service Act 1977* (e.g. Bristol) or a confidential inquiry under section 2 of the *National Health S Act 1977* (e.g. Royal Liverpool). Section 2 inquiries have no specific powers of inquiry. Both Houses of Parliament can order an inquiry pursuant to section 1 of the *Tribunal of Evidence (Inquiries) Act 1921* (e.g. Shipman). Section 2 and section 84 Inquiries have extremely broad powers of investigation conferred upon them by statute. The Healthcare Commission also has statutory powers to undertake inquiries if ordered to by the Department of Health under section 20 of the *Health Act 1999* and such investigations have very limited statutory investigations powers.

The methodology of every inquiry is different, except for Healthcare Commission inquiries for which attempts are being made to establish a standard methodology. The experience in the U.K. is that inquiries are always reaching similar conclusions, which suggests that "their recommendations are either misdirected or not properly implemented".[80] Many of the models of inquiry commonly used in the past (i.e. private inquiries whether external or internal) are not thought to be sufficiently transparent, fair, or rigorous. Therefore, some commentators suggest that in the absence of trust in the NHS and NHS mechanisms for inquiry there will be increasing dependence upon the more open types of inquiry such as public inquiries and inquiries by the Healthcare Commission.[81] However, statutory inquiries are slow, costly, and cumbersome.

In February 2006 the Police, the Department of Health and the Health and Safety Executive executed a "Memorandum of Understanding: Investigating Patient Safety Incidents Involving Unexpected Death or Serious Untoward Harm: A protocol for Liaison and Effective Communications between the National Health Service, Association

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[75] Deaths of hundreds of patients of a general practitioner who were allegedly murdered by that practitioner. Online: the Shipman Inquiry <http://www.the-shipman-inquiry.org.uk/>.
[76] Retention of body parts and tissue samples from children without knowledge or consent. Online: The Royal Liverpool Inquiry <http://www.rlcinquiry.org.uk/>.
[77] Gynecologist who was alleged to have committed numerous errors. Jean Ritchie, *An Inquiry into Quality and Practice within the National Health Service Arising from the Actions of Rodney Ledward* (London: Department of Health, 2000).
[78] U.K., Department of Health, Press Release, "Independent investigations into past events in three local NHS services" (13 July 2001) online: Department of Health <http://www.dh.gov.uk/PublicationsAndStatistics/PressReleases/PressReleasesNotices/fs/en?CONTENT_ID=4010808&chk=4Caxkq>.
[79] Kieran Walshe & Joan Higgins, "The Use and Impact of Inquiries in the NHS" (2002) 325:7369 B.M.J. 895.
[80] *Ibid* at 899.
[81] *Ibid*.

of Chief Police Officers and Health and Safety Executive."82 It is a protocol for liaising with each other so that investigations do not overlap and maximum cooperation is obtained between parties to an investigation.

Compensation Systems

England has a common law system where claims in respect of medical malpractice are settled through the tort system. In the financial year 1998/1999 the NHS (England) paid out £400 million in clinical litigation settlements and had a potential liability of around £2.4billion from existing and expected claims.[83] Claimants are somewhat hampered in the U.K., with the *Bolam* test (the defendant is not liable if a reasonable body of medical opinion supports the course of action taken) continuing to apply to allegations of negligence and informed consent. There are some indications that the House of Lords may be reconsidering this standard. Medical malpractice resulting in death is increasingly likely in the U.K. to attract the sanctions of the criminal law. More and more doctors whose errors result in death are being prosecuted for manslaughter.[84]

The NHS Litigation Authority was established in 1995 by the *National Health Service Litigation Authority (Establishment and Constitution) Order 1995*.[85] It is a special health authority mandated to administer schemes for the NHS to fund the cost of clinical negligence litigation through risk pooling arrangements. It aims to ensure that patients have appropriate access to remedies where liability is established, but also by "defending unjustified actions robustly, settling justified actions efficiently, and contributing to the incentives for reducing the number of negligent or preventable incidents."[86] It also has both educational and standard-setting functions for risk management.

In October 2005, the NHS Redress Bill was introduced in Parliament. This Bill went through second reading on November 2, 2005, and is presently in Committee for review. The Bill lays out a diversionary scheme for small claims in 'clinical negligence'. It is intended to reduce delays, provide greater coherence, and serve as an alternative to litigation. Its scope is tortious activities arising out of hospital services provided as part of the NHS, whether in the UK or abroad.

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[82] U.K., Department of Health, Association of Chief Police Officers, Health and Safety Executive, *Memorandum of Understanding: Investigating Patient Safety Incidents Involving Unexpected Death or Serious Untoward Harm: A protocol for Liaison and Effective Communications between the National Health Service, Association of Chief Police Officers and Health and Safety Executive*, online: DOH <http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4129918&chk=P5hkFZ>.

[83] *Memory, supra* note 16 at 5.

[84] Jon Holbrook, "The Criminalisation of Fatal Medical Mistakes: A Social Intolerance of Medical Mistakes has Caused them to be Criminalised" (2003) 327 BMJ 118. Since 1990, there have been 23 cases involving 28 doctors where manslaughter charges have been laid.

[85] *National Health Service Litigation Authority (Establishment and Constitution) Order* (U.K.), S.I./95-2800.

[86] NHS Litigation Authority, "Framework Document", online: <http://www.nhsla.com/home.htm>.

Qualifying liability in tort is defined as (a) in respect of personal injury or loss arising out of or in connection with breach of a duty of care owed to any person in connection with the diagnosis of illness, or the care or treatment of any patient, and (b) in consequence of any act or omission by a healthcare professional. Thus, slips and falls caused by wet floors, etc. are outside the scope of the statute.

An estate may sue on behalf of a deceased. Settlement agreements under the diversionary scheme include a waiver of the right to bring civil proceedings regarding the matter at hand. In the converse, the plaintiff may proceed civilly but proceedings under the scheme are terminated. The scheme is also to provide for the giving of an explanation except in specified circumstances (to be determined).

The most significant critique of the Bill as presently drafted is that the NHS Litigation Authority is to conduct the investigations. Thus, the institution that is allegedly responsible for the injury is also the one that sits in judgment on the matter. This lack of independence is of serious concern.

An additional critique is the lack of provision for specialist medico-legal advice, combined with the implicit retention of the *Bolam* test, which makes it difficult to establish negligence (and increases reliance on specialist opinions). This test was developed judicially; placing it in the hands of non-lawyers, i.e., the NHS, for application will cause problems.

The Bill also allows caps on various aspects of compensation, such as loss of earnings. The maxima under the various heads as well as for the total claim are left to be determined.

Other Patient Complaint Mechanisms

The United Kingdom has Ombudspersons (Health Service Commissioners)[87] to address concerns about National Health Services. There are three for each region: England, Wales and Scotland. The most recent legislation relating to the Health Service Commissioners is the *Health Service Commissioners Act 1993*.[88] Under this legislation, Health Services Commissioners may investigate regional health authorities, district health authorities, special health authorities, National Health Service trusts, Family Health Service Authorities, and other associated institutions in the National Health Service. At present, a complainant must first make a complaint to the institution that provided the service, and then the complainant may request an independent review. Only after the matter has not been resolved can a complaint be made to the Commission. The Commission can investigate a complaint from a person who claims that he or she has suffered 'injustice or hardship' as a result of a failure in service, a failure to provide a

[87] Parliamentary and Health Services Ombudsman (U.K.), online: <http://www.ombudsman.org.uk/hse>.
[88] *Health Service Commissioners Act 1993* (U.K.), 1993, c. 46.

service, or maladministration.[89] Up until 1993, the Commissioner was not able to conduct an investigation in respect of actions taken in connection with the diagnosis or care and treatment of a patient in the course of the exercise of clinical judgment. The Commissioner may only investigate services funded or provided by the National Health Service; it may not investigate private health services providers. It also cannot investigate matters that are before a court, will go before a court, or are subject to a public inquiry process.

The investigation process is private. The Health Services Commissioner makes an annual report to Parliament on the performance of its functions under the Act. In the period from April 2003 to March 2004, a record 4700 complaints about the NHS were made to the Health Service Commissioner for England (an 18 percent increase over the previous year). The Annual Report emphasizes that poor communication between doctors and patients, between health professionals, and between services is a significant problem. Poor complaint handling by NHS services was also highlighted, with delays, poor recordkeeping, and poor communication being highlighted as being problematic.[90]

Section 113 of the *Health and Social Care (Community Health and Standards) Act 2003* gives the Secretary of State the power to make regulations with respect to the handling and consideration of complaints made under the regulations about the exercise of the functions of an NHS body or Special Health Authority, or the provision of health care by an NHS body or Special Health Authority.

A new regulation for complaints handling in the NHS came into force in 2004 and applies to England.[91] Each NHS body must make arrangements to handle and consider complaints. Each NHS body must designate a member or a member of its board of directors to take responsibility for ensuring compliance with the regulations, and that action is taken in light of the outcome of any investigation,[92] and must appoint a complaints manager. It sets out a number of procedural requirements for complaint receipt and response. If the complainant is unsatisfied with the result of an investigation, an investigation has not been completed within six months of the date on which it was made, or a decision was made not to investigate, the complainant may request the Healthcare Commission to consider the complaint. The Healthcare Commission may not investigate if the complainant intends to bring legal proceedings, the Trust has commenced disciplinary actions, the matter relates to a data request, or the Health Service Commissioner is investigating or has investigated it.[93] Each NHS body must prepare an annual report for the Healthcare Commission on its handling and consideration of complaints.

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[89] *Ibid.*, s. 3.
[90] Health Service Ombudsman for England, *Annual Report 2003-2004* (London: Health Service Ombudsman, 2004) online at: Ombudsman <http://www.ombudsman.org.uk/hsc/document/har04/har04index.htm>.
[91] *The National Health Service (Complaints) Regulations 2004* (U.K.), S.I. 2004/1768.
[92] *Ibid.*, s. 4.
[93] *Ibid.*, s. 15.

Adverse Event Reporting Systems

There are a number of different reporting mechanisms used in the United Kingdom. Those relating to medical devices and pharmaceuticals are discussed in the products liability section.

In June 2000, the British Government accepted the recommendations made in *An Organisation with a Memory*.[94] The Report acknowledged that there has been little systematic learning from adverse events and service failure in the NHS in the past, and drew attention to the scale of the problem of potentially avoidable events that result in unintended harm to patients. The Report proposed solutions based on developing a culture of openness, reporting, and safety consciousness within NHS organisations. It proposed the introduction of a new national system for identifying adverse events and near misses in healthcare in order to gather information on causes, to learn, and to act to reduce risk and prevent similar events occurring in future. Accordingly, the National Patient Safety Agency was established in 2001 to:[95]

- collect and analyse information
- assimilate other safety related information
- learn lessons and ensure they are fed back into practice
- produce solutions to prevent harm
- specify national goals
- establish mechanisms to track progress

The NPSA co-ordinates the efforts of those involved in healthcare to learn from adverse incidents occurring in the NHS. As well as making sure that incidents are reported, the NPSA aims to promote an open and fair culture in hospitals and across the health service, encouraging doctors and other staff to report incidents and "near misses" (i.e., when things almost go wrong). It aims to do this by creating an environment where reporting can occur without fear of personal reprimand. It is more about the "how" of adverse events rather than the "who". It is not a performance management, regulatory or investigative body. The NPSA has no statutory powers to make the reporting of incidents mandatory or to compel organisations to act alerts and advice. However, as the aims of the NPSA are consistent with the statutory duties of Trusts in terms of quality, it is not expected that organizational compliance will be an issue.

The National Reporting and Learning System (NRLS) is administered by the National Patient Safety Agency and started in February 2004 (it is being rolled out across the country). It is an IT/web-based system that receives and records patient safety incidents. A patient safety incident is defined as any unintended or unexpected incident which could have led or did lead to harm for one or more patients receiving NHS-funded care. NHS staff may voluntarily and anonymously report incidents. The data is analysed to identify patterns, trends, and risks to patient safety, and to provide feedback. Three types of incidents are identified and recorded: those that have happened, those that have been

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[94] *Memory, supra* note 16.
[95] *National Patient Safety Agency (Establishment and Constitution) Order 2001* (U.K.), S.I./01-1743.

prevented, and those that might happen. Information is stored anonymously, although the NHS organization originating the report will be identifiable. Through national reporting, the NPSA hopes to develop an accurate picture of the extent of adverse incidents in the NHS in England and Wales, and to have a baseline against which to measure improvements in patient safety. It aims to understand and tackle the "root causes" behind incidents and, by sharing that information, to prevent the same incidents recurring. It aims to identify trends in the occurrence of, and reasons for, incidents. It issues safety alerts, for example, in relation to potassium chloride.

There are 31 patient safety managers, one for each Strategic Health Authority in England and for each NHS Region in Wales. The managers provide expertise, support and coordination to help develop and introduce the National Reporting and Learning System, support and advise NHS staff on patient safety issues, support NHS risk managers in the identification, management, investigation and reporting of patient safety incidents and risks, bring patient safety concerns to the attention of the NPSA, develop solutions, and provide leadership and advice on patient safety to NHS organizations in their area.

The NPSA has 17 Clinical Specialty Advisors who are appointed directly to the NPSA or through their Royal College or associated organisation. Their role is to:

- support the flow of information on patient safety issues within their specialty;
- encourage a collaborative approach towards the identification and assessment of the scope of patient safety issues;
- enable a collaborative approach to the development and implementation of solutions;
- place patient safety at the centre of the Royal College and other decision making bodies.

Some Clinical Specialty Advisors have established External Reference Groups which are representative of the different disciplines involved in delivering care within their specialty. Such groups:

- assist in the identification of key patient safety priorities within the specialty;
- provide the Clinical Specialty Advisors with the scope of medical and non-medical experience required to undertake a holistic analysis of the root causes of patient safety incidents identified as key priorities;
- provide input into the solutions developed to address issues and ensure that the outputs of this process are designed in a manner that will support their adoption by their peers;
- provide a network through which the NPSA can disseminate communications and solutions.

A recent report has suggested that the National Patient Safety Agency assume responsibility for research ethics, as it suggests that research ethics is "closely connected to patient safety and confidence."[96] It suggests that the National Patient Safety Agency accordingly take the national lead in supporting the development of ethics committees

[96] *Reconfiguring, supra* note 7 at 18.

that review clinical trials with medicines and also the development of NHS ethics committees. It also suggests that the NPSA take on responsibility for the Central Office of Research Ethics Committees from the Department of Health.

There are no evidentiary protections available through legislation. The common law applies using the *Wigmore* test and grants protections on a case-by-case basis.

Monitoring

There are a number of monitoring bodies in the United Kingdom/England.

Since 1999, the National Institute for Clinical Excellence has the responsibility to fund and oversee three inquiries which review information collected during day-to-day healthcare to recommend changes for the future (national confidential enquiries).[97] Previously, the Department of Health was responsible for funding and overseeing four confidential inquiries.[98] The inquiries examine anonymised data (although the Trust is identifiable). All relevant health providers are encouraged to participate in the work of the inquiries. The results are used by the National Institute for Clinical Excellence to create guidelines and standards (see Standards and Guidelines section). Each inquiry also feeds back information to the Trust to assist in internal education processes. Any case or trend that gives cause for concern is brought to the attention of the Trust concerned. A recent report recommends transferring the responsibilities for national confidential inquiries to the National Patient Safety Agency.[99]

The Healthcare Commission publishes performance data relating to the provision of healthcare by and for the NHS.[100] It must undertake an annual review of the provision of healthcare by each English NHS body and cross-border special health authority, taking into account standards set by the Secretary of State.[101] There is also provision for special reviews of the overall provision of healthcare by and for NHS bodies, the overall provision of particular kinds of healthcare, and the provision of healthcare or a kind of healthcare by an English NHS body as requested by the Secretary of State, again taking into account standards set by the Secretary of State. After a review, it must report to the Secretary of State or the Welsh Assembly any significant failings in regard to: the provision of healthcare; the running of an English NHS body or special authority; any individual providing health care for an English NHS body or cross-border special health authority. It may include recommendations. It may also report to the regulator. The Healthcare Commission may provide advice to the Secretary or the Assembly in relation to the provision of health care. It may also conduct reviews of the data collected by and for NHS bodies. It can also promote or undertake studies designed to enable it to make

[97] Confidential inquiries are occurring in respect of: Maternal and Child Health; Patient Outcome and Death; and Suicide and Homicide by People Using Mental Health Services.
[98] The maternal deaths inquiry commenced in 1951, peri-operative deaths in 1988, suicide and homicide in 1991, and still-born and deaths in infancy in 1991. It appears that maternal and still-born were merged by the Commission.
[99] *Reconfiguring*, *supra* note 7 at 16.
[100] *HSCA*, *supra* note 34, s. 49.
[101] *HSCA*, *supra* note 34, s. 50.

recommendations for improving economy, efficiency and effectiveness in the exercise of the functions of an NHS body. The results of such studies must be published.

In relation to independent (private) hospitals, independent clinics, and independent medical agencies, the Healthcare Commission's general duty is to encourage improvement in the quality of independent health services in England. It has a general duty to keep the Secretary of State informed about the provision of independent health services in England and, in particular, about the availability and quality of such services.[102] Information about independent health services is available to the public. The Commission may give advice and make recommendations to the Secretary at any time.

The NHS Estates conducts inspections and undertakes monitoring of building safety, food standards, and cleanliness.

The bodies listed above that have responsibilities for review and audit for the NHS in England have agreed to streamline inspections of organizations by agreeing on shared systems for assessment and data collection. The signatories (the National Audit Office, the Healthcare Commission, the Mental Health Commission, the Postgraduate Medical Education and Training Board, NHS Estates, Health and Safety Executive, Commission for Social Care Inspection and the Academy of Medical Royal Colleges) have agreed to establish a health and social care inspection forum. A database of inspection schedules will be developed to coordinate visits and will consider inspection holidays for those that perform well.[103]

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[102] *Care Standards Act 2000* (U.K.), 2000, c.14, s. 5A, as am. by *HSCA*, *supra* note 34, s. 103.

[103] Susan Mayor, "Regulatory Bodies Agree to Streamline NHS Inspections in England" (2004) 329:7456 BMJ 14. See also Commission for Healthcare Audit and Inspection, *Concordat Between Bodies Inspecting, Regulating and Auditing Healthcare* (London: Healthcare Commission, 2005), online: <http://www.healthcarecommission.org.uk>.

Patient Safety Law:
From Silos to Systems

Appendix 2: Country Reports
THE UNITED STATES OF AMERICA

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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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The United States of America

The United States of America is a Federal Republic. The country's population is approximately 294 million.

Health Care System Context

Law

The United States uses a common-law system but has law at the federal and state level.

Health

The foundation of the health care in the United States is weighted towards private finance and the market – it focuses on the supply of services rather than the ability to access services. Health care is not regarded as a social right in the United States, nor is it considered a universal entitlement.[1] While in most other industrialized countries the principles of universality, public financing and administration and expenditure controls are integral parts of health care systems, the United States is an outlier where employer-based benefits are the norm and public insurance is extremely limited.[2]

Health Services Delivery

The Federal government directly subsidizes the costs of care for some population groups and indirectly subsidizes health care through tax deductions for private insurance plans. The distinction between private and public sectors in the U.S. is essentially based on population categories. Government involvement is limited to dual-tiered system of federal and state programs – Medicare and Medicaid. The Medicare and Medicaid programs were established by the federal government in 1965 to provide financial assistance to the elderly, disabled and the poor. Medicaid is a social assistance program based on a means test that provides hospital and physician care to persons eligible for federal welfare benefits. The program reimburses private providers for services rendered. It is primarily administered by the states, but is jointly funded by federal and state governments. Medicare covers the elderly or disabled who are eligible for social security benefits. Part A covers inpatient hospital care and is directly paid by the federal

[1] Antonia Maioni, *Parting at the Crossroads* (Princeton, N.J.: Princeton University Press, 1998) at 8.
[2] *Ibid.*

government and financed by social security taxes on workers. Part B offers supplementary insurance for physician and outpatient services and involves deductibles and co-payments. Public expenditures on health care in the United States account for less than half of the total spending on health[3] (in 1997 46.7 percent of the national expenditure on health).[4] Only approximately 45 percent of the U.S. population is covered by publicly financed hospital insurance (based on 1997 figures)[5] and twenty-five percent have publicly funded medical coverage.[6] Of the Americans covered by private health insurance, 80 percent rely on benefits tied to employment.[7] An estimated 40 million Americans have no coverage – public or private – and that number increases each year. Millions more are 'under-insured' in that they may only be covered for hospital inpatient care, not physician services, outpatient care or pharmaceuticals. The Medicare and Medicaid programs are administered at the federal level by Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration). Part of the federal Department of Health and Human Services, CMS is a major federal agency, employing over 4,000 employees and concentrating on policy development, health care research, budget preparation and analysis, enforcement of health care quality standards and legislative analysis and liaison. The federal Department of Veterans Affairs provides medical services for those who have served in the armed forces in the United States. The Veterans Health Administration administers the provision of health services for veterans. The Centers for Disease Control and Prevention are the public health arm of the federal government.

The federal government's funding role in the health system is not generally directed at funding service provision, rather, as Jacobs states, "the U.S. Government's first and most generous involvement in health care focused on expanding the supply of hospital-centered, technologically sophisticated health care."[8] This is so generally because when the health system first developed, both the federal and state governments were weak and had few resources.[9] The power vacuum meant that the health care system was dominated by private interests, by organized professional group(s), elite medical researchers and supporters of capitalism.[10] Suppliers dominated the system so there was powerful support for the state's activities to be extended to infrastructure support. The *Hill-Burton Hospital Construction Act 1946* committed the federal government to financially supporting hospital construction ($3.7 billion spent in 35 years). Medical research in particular currently is, and was, heavily funded by the federal government, with one congressman calling it "the best kind of health insurance."[11] Federal research funding

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[3] *Ibid.*
[4] Organisation for Economic Co-operation and Development, *OECD Health Data, 1998* (Paris:OECD, 1998).
[5] *Ibid.*
[6] *Ibid.*
[7] *Ibid.*
[8] L. Jacobs, "Politics of America's Supply State: Health Reform and Technology" (1995) 14:2 Health Aff. 143 at 144-145.
[9] M. Moran, *Governing the Health Care State* (Manchester: Manchester University Press, 1999) at 42-43.
[10] *Ibid.* at 43.
[11] *Ibid.* at 46.

agencies include the National Institutes of Health and the Agency for Health Care Research and Quality.

The United States' expenditure on health as a percentage of GDP is the highest amongst OECD countries – in 1995 the U.S. spent 14 percent of its GDP on health care.[12] This is due to the complex multi-payer system which increases administrative costs and to a rapid increase in health care costs and demand. Government tried to contain the costs of health care through encouraging private sector initiatives.[13] For example, the Nixon government passed *The Health Maintenance Organization Act 1973* to encourage the development of prepaid group plans that could restrain expenditure by hospitals and physicians and centralize health care delivery (known as HMO's). By 1995, managed care became a dominant part of the U.S. health system administered by HMO's. Managed care can be defined as "health plans that contract selectively with providers on a discounted basis and provide utilization management and quality assurance".[14] Basically, third-party funders contract with doctors on the terms of service delivery; patients no longer control usage and charging through individual encounters between them and a physician. Decisions about the provision of health care are therefore made by autonomous corporations and medical practitioners. Federal and state governments also directly regulate the private insurance market through micro-regulation of the provision of health care, using such tools as anti-trust regulation and competition law.

Performance

The Commonwealth Fund's International Working Group on Quality Indicators compares forty quality indicators from five countries: Australia, Canada, New Zealand, the United Kingdom and the United States.[15] Each country studied had different areas of good performance and weakness. The U.S. had the highest breast cancer survival rates and cervical screening rates were very high. Waiting times for elective surgery were the lowest. U.S. doctors were most likely to ask for the patient's opinion and to discuss the emotional burden of illness. Although decreasing in other countries, asthma mortality rates are increasing in the U.S. U.S. citizens reported trouble seeing doctors, particularly on nights and weekends and for same day appointments. They also reported the most financial barriers to care and the most coordination of care problems.

The World Health Organization examined the relative performance of health systems of member countries.[16] Overall health system attainment (this measures the level of health,

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[12] OECD, *supra* note 4.
[13] Maioni, *supra* note 1 at 167.
[14] J. Gabel, "Ten Ways HMOs Have Changed During the 1990's" (1997) 16:3 Health Aff. 134 at 144.
[15] Commonwealth Fund International Working Group on Quality Indicators, *First Report and Recommendations of the Commonwealth Fund's International Working Group on Quality Indicators: A Report to Health Ministers of Australia, Canada, New Zealand, the United Kingdom and the United States June 2004* (New York, Commonwealth Fund, 2004) online: Commonwealth Fund <http://www.cmwf.org>.
[16] The World Health Organization, *The World Health Report 2000* (Geneva: The World Health Organization, 2004).

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 the U.S. ranked fifteen on the list (Canada 7, Australia 12, U.K. 9, Denmark 20 and N.Z. 26).[17] The study also examined how efficiently health systems translate expenditure into health in regard to the overall achievement to expenditure. The U.S. ranked number 37 in the world (Canada 30, U.K. 18, Australia 32, Denmark 34, and New Zealand 41).[18] The responsiveness of health systems was also examined in regard to the level of responsiveness (defined as dignity, autonomy, confidentiality, prompt attention, quality of basic amenities, access to social support networks during care and the choice of care provider). The U.S. ranked one (U.K. 26-27 (with Qatar), Denmark 4, Canada 7-8, Australia 12-13, New Zealand 22-23). In terms of the distribution of responsiveness (in relation to disadvantaged groups), the U.S. ranked third, making it equal with 37 other countries including the U.K., N.Z., Canada, Denmark and Australia.

In 2000, the Institute of Medicine released its seminal text – *To Err is Human*.[19] In this report, it concludes that health care needs to move beyond blaming individuals for retrospective events and focus on preventing future errors by designing safety into the system. It made a number of recommendations - the following relate recommended changes to or use of law:

1) Congress should "establish a Center for Patient Safety within the Agency for Healthcare Research and Quality. This center should:
   - set the national goals for patient safety, track progress in meeting these goals, and issue an annual report to the President and Congress on patient safety; and
   - develop knowledge and understanding of errors in health care by developing a research agenda, funding Centers of Excellence, evaluating methods for identifying and preventing errors, and funding dissemination and communication activities to improve patient safety.

2) A nationwide mandatory reporting system should be established that provides for the collection of standardized information by state governments about adverse events that result in death or serious harm. Reporting should initially be required of hospitals and eventually be required of other institutional and ambulatory care delivery settings. Congress should:
   - designate the National Forum for Health Care Quality Measurement and Reporting as the entity responsible for promulgating and maintaining a core set of reporting standards to be used by states, including a nomenclature and taxonomy for reporting;
   - require all health care organizations to report standardized information on a defined list of adverse events;

[17] Because of statistical uncertainty Canada, the U.K. and Australia are in the same range with less than 0.5 percent difference between them.
[18] Canada, Australia and Denmark are in the same range.
[19] Institute of Medicine, *To Err is Human: Building a Safer Health System*, (Washington, D.C.: National Academy Press, 2000) [To Err].

• provide funds and technical expertise for state governments to establish or adapt their current error reporting systems to collect the standardized information, analyze it and conduct follow-up action as needed with health care organizations. Should a state choose not to implement the mandatory reporting system, the Department of Health and Human Services should be designated as the responsible entity; and
• designate the Center for Patient Safety to:

(a) convene states to share information and expertise, and to evaluate alternative approaches taken for implementing reporting programs, identify best practices for implementation, and assess the impact of state programs; and

(b) receive and analyze aggregate reports from states to identify persistent safety issues that require more intensive analysis and/or a broader-based response (e.g., designing prototype systems or requesting a response by agencies, manufacturers or others).

3) The development of voluntary reporting efforts should be encouraged. The Center for Patient Safety should:

• describe and disseminate information on external voluntary reporting programs to encourage greater participation in them and track the development of new reporting systems as they form;
• convene sponsors and users of external reporting systems to evaluate what works and what does not work well in the programs, and ways to make them more effective;
• periodically assess whether additional efforts are needed to address gaps in information to improve patient safety and to encourage health care organizations to participate in voluntary reporting programs; and
• fund and evaluate pilot projects for reporting systems, both within individual health care organizations and collaborative efforts among health care organizations.

4) Congress should pass legislation to extend peer review protections to data related to patient safety and quality improvement that are collected and analyzed-by health care organizations for internal use or shared with others solely for purposes of improving safety and quality.

5) Performance standards and expectations for health care organizations should focus greater attention on patient safety.

• Regulators and accreditors should require health care organizations to implement meaningful patient safety programs with defined executive responsibility.
• Public and private purchasers should provide incentives to health care organizations to demonstrate continuous improvement in patient safety.

6) Performance standards and expectations for health professionals should focus greater attention on patient safety. Health professional licensing bodies should:

(a) implement periodic re-examinations and re-licensing of doctors, nurses, and other key providers, based on both competence and knowledge of safety practices; and
(b) work with certifying and credentialing organizations to develop more effective methods to identify unsafe providers and take action.

7) Professional societies should make a visible commitment to patient safety by establishing a permanent committee dedicated to safety improvement. This committee should:

(a) develop a curriculum on patient safety and encourage its adoption into training and certification requirements;
(b) disseminate information on patient safety to members through special sessions at annual conferences, journal articles and editorials, newsletters, publications and websites on a regular basis;
(c) recognize patient safety considerations in practice guidelines and in standards related to the introduction and diffusion of new technologies, therapies and drugs;
(d) work with the Center for Patient Safety to develop community-based, collaborative initiatives for error reporting and analysis and implementation of patient safety improvements; and
(e) collaborate with other professional societies and disciplines in a national summit on the professional's role in patient safety.

8) The Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre and post-marketing processes through the following actions:

• develop and enforce standards for the design of drug packaging and labeling that will maximize safety in use;
• require pharmaceutical companies to test (using FDA-approved methods) proposed drug names to identify and remedy potential sound-alike and look-alike confusion with existing drug names; and
• work with physicians, pharmacists, consumers, and others to establish appropriate responses to problems identified through post-marketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.[20]

The Institute of Medicine released *Crossing the Quality Chasm* in 2001.[21] The IOM concluded, "In its current form, habits, and environment, American health care is incapable of providing the public with the quality health care it expects and deserves."[22] It calls for improvements in six dimensions of health care performance: safety; effectiveness; patient-centeredness; timeliness; efficiency; and equity. It suggests that improvements cannot be made within the current U.S. healthcare system and advocates

[20] *Ibid.* at 1-15.
[21] Institute of Medicine, *Crossing the Quality Chasm: A New Health System for the 21st Century* (Washington DC: National Academy Press & Institute of Medicine, 2001).
[22] *Ibid.* at 43.

for the redesign of the U.S. health care system at four levels: patients' experiences (level A); the small units of care delivery (microsystems) (level B); organizations that house and support microsystems (level C) and the environment of laws, rules, payment, accreditation and professional training that shape organizational action (level D).[23] The quality of actions at level B, C, D ought to be defined as the effects of those actions at level A. It endorsed the following statement on the purpose for the U.S. health care system suggested by the President's Advisory Committee: "the purpose of a health care system is to reduce continually the burden of illness, injury, and disability and to improve the health status and function of the people of the United States." The IOM suggested the following six "Aims for Improvement:"

- Safety – patients should be as safe in health care facilities as they are in their own homes.
- Effectiveness – the health care system should match care to science, avoiding both the overuse of ineffective care and the under-use of effective care.
- Patient-centeredness – health care should respect the patient's choices, culture, social context, and specific needs.
- Timeliness – care should continually reduce waiting times and delays for patients and care providers.
- Efficiency – the reduction of waste and the reduction of the total cost of care should be never-ending, including for example waste of supplies, equipment, space, capital, ideas and human spirit.
- Equity – the system should seek to close racial and ethnic gaps in health status.

Patient Safety

Key Statistics

A number of studies in the U.S. have identified significant patient safety related problems in U.S. hospitals. The earliest studies were the Harvard Medical Practice study conducted in 1991, which estimated an adverse event rate of 3.7 percent with a death or permanent disability rate of 0.7 percent.[24] Similar results were found in the course of another study conducted at the same time (Utah/Colorado study).[25] In 2000, the Institute of Medicine published a report entitled *To Err is Human*, which drew attention to the new emerging statistical reality that as many as 98,000 Americans die each year as a result of medical

[23] See also, Donald Berwick, "A User's Manual for the IOM's 'Quality Chasm' Report" (2002) 21:3 Health Affairs 80.

[24] T.A. Brennan *et al.* "Incidence of Adverse Events and Negligence in Hospitalized Patients. Results of the Harvard Medical Practice Study I" (1991) 324:6 N. Engl. J. Med. 370 and L.L. Leape, T.A. Brennan, *et al*., "The Nature of Adverse Events in Hospitalized Patients: Results from the Harvard Medical Practice Study II" (1991) 324:6 New Engl. J. Med 377.

[25] Eric Thomas, DM Studdert, Helen Burstin, *et al*. *Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado* (2000) 38:3 Med. Care 261.

error.[26] A more recent (2004) study of the pediatric population in the United States suggests that medical errors are responsible for the deaths of nearly 4,500 children in the U.S. every year and cost more than $1 billion per year. Children less than one year old and those covered by Medicaid (i.e. the poor) were more likely to experience medical errors.[27] Another 2004 study by the same authors examined the impact of medical injuries and concluded that more than 30,000 patients died each year.[28]

Institutional Regulation

Institutional regulation occurs at both the federal and state level. In addition, the acceptance of private accreditation by certain federal and state regulators as a means of satisfying program participation or licensure requirements makes accreditation significant. For example, federal law allows institutions to be deemed as meeting the Conditions of Participation for Medicare if they are accredited by the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO), a non-profit organization that accredits over 15,000 healthcare facilities in the United States.[29] JCAHO sets standards against which health care facilities are accredited and recent initiatives include standards concerning wrong site, wrong procedure or wrong person surgery.[30] Their standards are widely followed, as meeting JCAHO requirements is one mechanism for facilities to qualify for Medicare.

At the federal level, the Centers for Medicare and Medicaid Services (CMS) administer the Medicare program and jointly administer the Medicaid program with states. Health care organizations seeking to participate in the programs must be certified as complying with the Conditions of Participation and Condition of Coverage requirements appropriate for their organization.[31] These conditions contain standards intended to "improve quality and protect the health and safety of beneficiaries."[32] Hospitals seeking to participate are required to meet standards pertaining to patient rights, quality improvement, staffing, infection control and numerous other areas of hospital operation.[33] In 2003, a new condition of participation was implemented using a performance improvement

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[26] Institute of Medicine, *To Err supra* note 19.

[27] M. Miller & C. Zhan, "Pediatric Patient Safety in Hospitals: A National Picture in 2000" (2004) 113:6 Pediatrics 1741. The study is not without its critics who charge that it grossly overstates the impact of medical errors because it included deaths that could not unequivocally be attributed to mistakes. Anne Harding, "Study Finds US Paediatric Medical Errors Kill 4500 Children a Year" (2004) 328:7454 BMJ 1458.

[28] C. Zhan & M. Miller, "Excess Length of Stay, Charges, and Mortality Attributable to Medical Injuries During Hospitalization" 2003 290:14 JAMA 1868.

[29] Deemed Status for JCAHO accreditation is found in section 1865 of the *Social Security Act* and in regulations at 42 C.F.R. 488.5. Accredited hospitals will not be deemed to meet a condition of participation that CMS identifies as being higher or more precise than JCAHO's requirements.

[30] Scott Gottlieb, "United States Brings in New Rules to Prevent Surgical Errors" (2004) 329:7456 BMJ 13.

[31] For a list of rules and regulations governing each type of organization, see CMS, *Conditions of Participation, Conditions of Coverage Citations*" online: CMS < http://www.cms.hhs.gov/cop/1.asp>.

[32] *Ibid.*

[33] 42 C.F.R. § 482 (2003).

framework that requires hospitals to "develop, implement and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program" or QAPI. [34] Designed to set a clear expectation that hospitals must take a proactive approach to improving their performance, this condition is a minimum requirement for hospitals to both systematically examine their quality and undertake ongoing improvement projects.[35] A hospital's QAPI program must:

- include an ongoing program that shows measurable improvement in relation to indicators for which there is evidence that it will improve health outcomes and reduce medical errors. Hospitals are required to measure, track and analyze quality indicators, including adverse patient events;
- incorporate quality indicator data. Data the hospital collects should be used for monitoring the effectiveness, safety and quality of services and identifying improvement strategies;
- set priorities for improvement activities, which involves focusing on high-risk, high volume areas that affect health outcomes and patient safety. These activities must involve tracking adverse patient events and medical errors, studying their causes, and implementing preventative actions and feedback and learning mechanisms throughout the hospital.
- include distinct performance improvement projects. The number and scope of the projects conducted by the hospital must be proportional to the scope and complexity of the hospital's operation and be similar in effort to projects conducted by CMS contracted quality improvement organizations (QIOs).

The regulation makes the hospital's governing body accountable for ensuring the ongoing program for patient safety and quality improvement is well defined, implemented, maintained and adequately funded.[36] Considerable discretion is given to hospitals to design their program in an effort to increase flexibility and reduce regulatory burden, while maintaining an appropriate level of accountability.[37] Compliance with the QAPI regulatory framework is assessed by state agency surveyors, who survey a certain number of hospitals each year to determine whether they are compliant with the applicable conditions of participation.[38] Hospitals are required to show through the use of objective data that improvements have occurred in relation to actual care outcomes or other performance indicators as a result of their QAPI program.[39] If the hospital is significantly non-compliant with the QAPI requirements, it may be terminated from the Medicare or Medicaid programs.[40]

In addition to the survey process, CMS uses the Quality Improvement Organization (QIO) program as a mechanism to ensure that medical care paid for under the Medicare

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[34] 42 C.F.R. § 482.21 (2003). The regulation was made under *Social Security Act* § 1861(e), 42 U.S.C. 1395x (2005).
[35] 68 Fed. Reg. 3435-3436 (Jan. 24, 2003)
[36] 42 C.F.R. § 482.21(e) (2003).
[37] 68 Fed. Reg. 3437 (Jan. 24, 2003).
[38] Surveys are conducted pursuant to *Social Security Act* §1864, 42 U.S.C. 1395aa (2005).
[39] 68 Fed. Reg. 3443 (Jan. 24, 2003).
[40] 68 Fed. Reg. 3436 (Jan. 24, 2003).

program is medically necessary and reasonable, is of a quality that meets professionally recognized standards of health care and is provided in the most economical setting.[41] Under the program, CMS contracts with 53 independent organizations (one for each state, territory and the District of Columbia) to monitor and improve the quality of care delivered to beneficiaries. Under the Act, the organization must be composed of a substantial number of physicians and have at least one individual who is a consumer representative on its governing body.[42] Each quality improvement organization (QIO) is governed by a three year contract, known as a Statement of Work (SOW), which outlines their responsibilities and is divided into tasks.[43]

Quality review mechanisms for Medicare have evolved over time and reflect CMS's "transition from a financing program to a value based purchaser of health care."[44] Utilization and Quality Control Peer Review Organizations (PROs) were created by Congress in 1982[45] to replace controversial professional standards review committees (PSROs).[46] Earlier contract cycles focused on individual case review and the reduction of inappropriate admissions to hospitals. By the early 1990s, an evolving awareness emerged among stakeholders that retrospective individual case analysis was an ineffective means of improving the overall quality of health care. Later contract cycles moved to a quality improvement approach and the primary activity of the PROs became collaboration with stakeholders to implement quality improvement projects in areas of clinical concern.[47] These projects typically focus on clinical care processes known to improve patient outcomes or specific preventative services and improvements in care are measured using national disease specific quality of care measures.[48] For example, one current measure of the quality of care involving pneumonia used by CMS is whether

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[41] Currently known as Quality Improvement Organizations (QIOs), these functions of utilization and quality control peer review organizations are set out in section 1154 of the *Social Security Act* § 1154, 42 U.S.C. § 1320c-3 (2005). Further information on what norms of care are to be applied by QIOs is contained in Social Security Act § 1154 (a)(6)(A).

[42] *Social Security Act* § 1152, 42 U.S.C. § 1320c-1 (2005).

[43] *Social Security Act* § 1153, 42 U.S.C. § 1320c-2 (2005).

[44] V. Bhatia *et al*. "Evolution of Quality Review Programs for Medicare: Quality Assurance to Quality Improvement" (2000) 22:1 Health Care Finan. Rev. at 73.

[45] *Peer Review Improvement Act 1982***,** Pub. L. No. 97-248, 96 Stat. 381(amending *Social Security Act*, Title XI Part B).

[46] PSROs were created in the 1970s to ensure quality care and to check rapidly rising Medicare hospital costs. They were widely viewed as a mechanism for controlling costs and medial practice, rather than improving quality of care and it is widely agreed they were unsuccessful in accomplishing either goal. Their reputation was as torpid watchdogs, lacking authority, and in many cases the desire to question doctors' decisions. See Bhatia *et al*. *supra* note 44 and Spencer Vibbert, *The Doctor Watchers* (Ground Rounds Press & Whittle Direct Press, 1991) at 15.

[47] It should be noted that while QIO activity has been focused on quality improvement, there are indications that in the 8th SOW there will be activities more directly focused on patient safety. A summary of the draft 8th SOW requires QIOs to work with select rural or low volume hospitals to implement a safety culture and redesign systems to address local patient safety issues. Centers for Medicare and Medicade, Services, Office of Clinical Standards and Quality, Quality Improvement Group, "Proposed Summary of Draft 8th Statement of Work: Task 1c2 Rural/Low Hospital" (2004) at 8, online: <www.ahqa.org/pub/uploads/8SOWExecSummaryv5.doc>

[48] CMS, *Statement of Work, Group Three Contracts* online: CMS <http://www.cms.hhs.gov/qio/2l.pdf>. Quality of care measures are defined in the SOW as "measures of how often these critical processes or services are performed or how often desired outcomes are achieved."

pneumonia patients at a hospital received their first dose of antibiotics within four hours of arrival.[49] Begun in 1999, the 6th Statement of Work (SOW) contract directed PROs to improve care in six clinical areas (AMI, heart failure, stroke, pneumonia, breast cancer and diabetes) that are major sources of mortality and morbidity for the Medicare population. Twenty-four process of care measures were developed in these areas and were based on scientific evidence and consensus that these processes can improve outcomes. A study that analyzed whether quality of care for Medicare beneficiaries had improved based on 22 of these indicators concluded that while care had improved, the data could not conclusively indicate the degree to which the improvements were tied to QIO's quality improvement efforts.[50] However, the study cites earlier evidence that suggests QIO interventions can lead to improvements, based on an analysis of a 1992 Cooperative Cardiovascular Project (CCP) implemented by PROs, where assistance given to providers to change care processes for AMI in four pilot states resulted in improved outcomes.[51] Under Section 109 (d) of the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA) , the Institute of Medicine (IOM) will conduct a study of the QIO program and its effectiveness and a report, including any legislative recommendations, is to be submitted to Congress no later than June 1, 2006.[52]

The MMA also has a provision that requires acute care hospitals to report a set of 10 hospital quality measures to CMS (through QIOs) in order to receive the full annual payment update from Medicare.[53] Eligible hospitals who fail to report on these indicators during the 2005-2007 fiscal period will have their annual payment update reduced by 0.4 percent. This statutory provision is intended to promote the public reporting of hospital quality data, which in turn is designed to help consumers make informed decisions about hospital care and to give hospitals incentives to improve their performance.[54] As of September 2004, 98.3 percent of eligible hospitals had satisfied the reporting requirements. As of April 2005, hospital performance data concerning the 10 measures, along with other measures voluntarily reported by hospitals through the Hospital Quality Alliance (HQA) project, is publicly available on the *Hospital Compare* website.[55]

Institutions are also regulated through state licensure laws, which set out minimum requirements for the institution's structure and operating processes in order for the facility to legally operate. Some states are incorporating patient safety into their hospital

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[49] These indicators are reportable to CMS under the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) initiative.

[50] Stephan Jencks, "Changes in Quality of Care Delivered to Medicare Beneficiaries, 1998-1999 to 2000-2001" (2003) 289:305 JAMA 312.

[51] Study limitations included the lack of a comparator group and the fact that the four states were not a random sub-sample of the country. See T. Marciniak *et al* "Improving the Quality of Care for Medicare Patients with Acute Myocardial Infarction" (1998) 279 JAMA 1351.

[52] *Medicare Prescription Drug Improvement and Modernization Act of 2003*, Pub. L. No. 108-173, 117 Stat. 2066.

[53] *Ibid.* at § 501(b).

[54] CMS, *Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) August 2005* online: CMS <http://www.cms.hhs.gov>; CMS, *Nearly All Eligible Hospitals are Reporting Quality of Care Data*, (2004) online: CMS <http://cms.hhs.gov>.

[55] See <www.hospitalcompare.hhs.gov>.

licensure laws. In order to be licensed in Florida, hospitals must have in place a patient safety plan, a patient safety officer and a patient safety committee, which will promote patient safety and help implement, review and evaluate the quality of the hospital's patient safety measures.[56] The hospital must also have in place an internal risk management program that includes an adverse incident reporting system, risk management education and training, and the development and implementation of procedures and systems to prevent wrong patient, wrong site, and wrong surgery procedure errors.[57] The law makes the hospital's governing board accountable for the internal risk management program. Nevada, New Jersey, and Washington have similar requirements. Other states have requirements for quality assurance or patient safety programs in specific facilities (in DC adult and pediatric trauma facilities, in Florida hospices and in Texas ambulatory surgical centers).

The quality of care in nursing homes has been a significant issue in the U.S. for more than thirty years. In 1986, the Institute of Medicine published a report that set out detailed recommendations for reforming the regulation of nursing homes.[58] The recommendations were largely accepted at the federal level and were enacted in the *Nursing Home Reform Act* as part of the *Omnibus Budget Reconciliation Act of 1987*. CMS is responsible for producing and maintaining federal regulations that all nursing homes interested in participating in Medicare and Medicaid must conform to (60 percent of the $90 billion spent in 1999 on nursing home care was borne by the states and federal government).[59] The state survey, licensing and certification agencies are responsible for surveying or inspecting nursing homes to check compliance with regulations, investigating complaints and reporting results to the CMS. State agencies and regional officers of CMS are responsible for taking enforcement action when deficiencies are identified. The Centers fund most costs of Medicare/Medicaid certification and oversees the performance of the state survey agencies. Nursing homes must also comply with state licensing requirements. In addition to the more general regulatory requirements set out in such statutes, some states have initiatives specifically aimed a safety in long-term care facilities. North Carolina, for example, has required that the Department of Health and Human Services contract with an entity to develop and implement a Medication Error Quality Initiative for nursing homes to analyze reports from each nursing home on the aggregate number of medication errors by type and cause.[60]

However, a number of bodies continue to publish reports that are critical of the regulation of nursing homes, including the Special Senate Committee on Aging, the U.S. General Accounting Office, and the Institute of Medicine, which revisited nursing home regulation and concluded that further reform is needed. The Clinton administration launched a nursing home initiative in 1998 aimed at improving the effectiveness of regulation.

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[56] Fla. Stat. § 395.1012 (2005).
[57] *Ibid.* at § 395.0197.
[58] Committee on Nursing Home Regulation, Institute of Medicine, *Improving the Quality of Care in Nursing Homes* (Washington DC: National Academy Press, 1986).
[59] Kieran Walshe, "Regulating U.S. Nursing Homes: Are We Learning From Experience?" (2001) 20:6 Health Aff. 128.
[60] N.C. Gen. Stat. § 131E-128.5.

There is some evidence to suggest that the quality of care in nursing homes may have improved in the last ten to fifteen years and that some of these improvements may be attributed to regulation. For example, the rates of physical and chemical restraint have reduced, as have the rates of urinary incontinence and catheterization. Hospital admission rates have also decreased. However, pressure sore rates have not changed and malnutrition, dehydration and feeding problems remain common, while bowel incontinence has increased.[61]

Critics suggest that there should be further reforms. One camp argues that regulatory standards should be toughened and more aggressively enforced. There should be more frequent inspections, greater use of sanctions and penalties and more uniform and rigorous application of existing regulations. The other camp believes that the regulatory burden is too great. They suggest regulation should be simplified and focused on the small number of problem nursing homes and reoriented towards a partnership model. Critics also note that regulatory fragmentation is a critical issue in nursing home regulation. Federal responsibility is split between national and regional offices and there is evidence to suggest that this causes communication problems and reduces the effectiveness of regulation. Responsibility is also split between regional federal offices and state survey agencies and conflicts may arise for the state agencies, which are accountable to the federal agency and to the state government. Federal and state regulation run side by side and this may result in duplication, conflicts and confusion.[62] Critics also note that there must be a balance between accountability and independence. They note that nursing home regulation is often a highly politicized process, which may result in risk averse and cautious regulators. They also highlight the conflict between the state and federal governments' dual roles as funders and regulators, noting that any move to tighten regulations to improve quality results in pressure for the government to spend more on reimbursements.

Working Conditions Regulation

Union negotiations over work conditions for medical residents were not possible in the U.S. until 1999, when the National Labor Board overturned twenty years of precedent by recognizing that medical residents were employees and allowing them the right to collective bargaining.[63] However, very few resident groups have sought to exercise collective bargaining rights.

In 2001, the Public Citizen Health Research Group, the American Students Medical Association, the Committee of Interns and Residents and others petitioned the federal Occupational Safety and Health Administration to regulate the work hours of residents.

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[61] Walshe, *supra* note 59.
[62] Walshe, *supra* note 59.
[63] *Boston Medical Center Corporation v House Officers' Association/Committee of Interns and Residents* 330 N.L.R.B. 152 (1999).

The Administration rejected the petition on the grounds that the ACGME, a private sector agency, should be responsible for work hour restrictions.[64]

The working hours problem in relation to health providers has excited legislative interest in the United States. Two states, New York and Puerto Rico, have legislation limiting work hours, although similar legislation is being considered by a number of states including Massachusetts, Delaware, New Jersey, Pennsylvania and California.

In New York, legislation was enacted as the result of the death of Libby Zion in a New York hospital. [65] Her father claimed that his daughter died because of inadequate care from overworked and under-supervised medical house officers. A grand jury was convened and found problems with the system of residency training and physician staffing that routinely allowed resident-physicians to work more than 100 hours per week for thirty to forty continuous hour periods. The grand jury found that over-worked, sleep-deprived residents and lack of supervision were serious potential dangers for patients and that the method of training doctors was "counterproductive to providing quality medical care".[66] A committee was established in 1987 to review the grand jury's findings. It recommended that a resident's scheduled workweek should be limited to 80 hours averaged over a four week period. Residents should not be scheduled to work shifts exceeding 24 consecutive hours and residents should have at least one scheduled 24 hour period of non-working time per week.

In 1989, the recommendations became part of the *New York State Health Code*, as revision to section 405.[67] The legislation requires 24 hour supervision of acute care inpatient units by an experienced attending physician, 12 hour work limits for residents and attending physicians in emergency departments, work periods not exceeding 24 hours in other departments, scheduled work weeks for residents not exceeding an average of 80 hours per week over four weeks and at least one 24 hour non-working period per week and ancillary support for resident physicians. In addition, the legislation provided hospitals with $240 million (U.S.) a year for eight years to hire more ancillary staff and board certified physicians. Compliance was 'voluntary'.

The most significant problem with this legislation was that it was routinely ignored. In 1998, the New York State Department of Health conducted a four day unannounced investigation of 12 hospitals across New York State. All 12 were found to be flagrantly violating the resident working hour limits, although supervision was appropriate. Findings were that: 37% of residents were working more than 85 hours per week; 20% exceeded 95 hours per week; 60 percent of surgical residents exceeded 95 hours per week and 38% of residents worked in excess of 24 hours per week. Residents also reported

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[64] See Hal Lawrence, "The Impact of Residents' Work-Hour Restrictions" (2003) 3 Current Womens' Health Rep. 487.

[65] N.Y. Comp. Codes & Regs tit. 10, § 405.4 (2004).

[66]. Supreme Court of the State of New York, County of New York. Part 50. Report of the Fourth Grand Jury for the April/May Term of 1986 Concerning the Care and Treatment of a Patient and the Supervision of Interns and Junior Residents at a Hospital in New York County. New York: Supreme Court of the State of New York; 1986: 50.

[67] N.Y. Comp. Codes & Regs tit. 10, § 405.4 (2004).

busy on-call time with limited rest.[68] In 2002, 66 percent of hospitals surveyed were not in compliance with the regulations. Fifty-six percent violated the 24 hour requirements, 34 percent violated the 80 hours per week requirements, 23 percent did not provide 24 hours off and 13 percent did not provide the required hours off between shifts.[69]

Puerto Rico recently passed an *Act to Regulate the Work Shifts of medical interns and residents in Puerto Rico*.[70] The Puerto Rican legislation dictates that resident work hours be limited to 80 hours a week, 24 hour shifts, and duties only every third night. Emergency Department shifts are limited to 12 hours, with exceptions from the Secretary of the Health Department of Puerto Rico allowing a maximum of 15 hours. Emergency Department shifts must be separated by at least 10 hours off, according to the Act, while all other shifts must be separated by 8 hours. Residents must also have one day off per week. The Act specifies no additional shift hours for non-patient duties (i.e. no additional hours for administration or learning) and moonlighting is prohibited once a resident reaches the maximum 80 hours for that week. Penalties for violations include a fine of up to $5,000 for programs and a fine of up to $200 for each resident. A committee established within the Health Department will handle complaints.

A House Committee of the United States Congress is considering the *Patient and Physician Safety and Protection Act of 2005*.[71] The 2005 Bill intends to reduce work hours and increase supervision of resident-physicians to ensure the safety of patients and the resident-physicians. The Preamble notes:

- Federal government spends $8 billion per year to train resident-physicians and therefore has an interest in assuring the safety of patients and residents
- Residents perform a significant amount of time performing activities not related to training
- The excessive numbers of hours worked by residents is inherently dangerous for patient care and for the lives of the residents
- The scientific literature has demonstrated that sleep deprivation of the magnitude seen in residency training programs leads to cognitive impairment
- A substantial body of research indicates that excessive hours worked by resident physicians leads to higher rates of medical error, motor vehicle accidents, depression and complications in pregnancy
- The medical community has not adequately addressed the problem
- The effects of sleep deprivation on resident physicians does not change between specialties
- The federal government has regulated the work hours of other industries when the safety of employees or the public is at risk

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[68] Rita Kwan & Robert Levy, *A Primer on Resident Work Hours: 5th Edition August 2004* (Reston VA: American Medical Student Association, 2004).
[69] Lawrence, *supra* note 64.
[70] *An Act to Regulate the Work Shifts of medical interns and residents in Puerto Rico* [2003] P.R. Laws 47. An English translation is available online at: American Student Medical Association <http://www.amsa.org/hp/rwh_pr.doc>.
[71] U.S. Bill H.R. 1228, *Patient and Physician Safety and Protection Act of 2005*, 109th Cong., 2005.

The Bill states that residents may work no more that a total of eighty hours per week and 24 hours per shift. There shall be at least ten hours between shifts, one full day off a week and one full weekend off a month. In an emergency department a resident shall work no more than 12 continuous hours and shall not be scheduled on call more often than every third night. A resident may file an anonymous complaint and a hospital may be fined up to $100,000 per program in any six month period. A person appointed by the Secretary of Health and Human Services anonymously surveys residents, conducts on site investigations, publicly discloses violations and reports to Congress. The Bill also allows the provision of extra funding to enable compliance.

The hours worked by nurses are also subject to attempted legislative intervention. A Committee of the U.S. Congress is currently examining the *Safe Nursing and Patient Care Act of 2005*.[72] The Bill intends to provide for patient protection by limiting the number of mandatory overtime hours a nurse may be required to work in Medicare funded facilities. The Preamble notes:

- The Federal Government has a substantial interest in assuring that delivery of health care services to patients in health care facilities is adequate and safe.
- The widespread practice of requiring nurses to work extended shifts and forego days off causes nurses to frequently provide care in a state of fatigue, contributing to medical errors and other consequences that compromise patient safety.
- Limitations on mandatory overtime will ensure that health care facilities throughout the country operate in a manner that safeguards public safety and guarantees the delivery of quality health care services and facilitates the retention and recruitment of nurses.

The Bill provides that a nurse should not be required to work more than any of the following: the scheduled work shift or duty period of the nurse; 12 hours in a 24-hour period; or 80 hours in a consecutive 14-day period. The Bill gives nurses the right to complain of violations free from retaliatory or discriminatory actions by providers. Providers who violate the provisions can receive a fine up to 10,000 and will have their names posted a DHHS website. The legislation also requires a study to determine the maximum length of time it is safe for a nurse to work.

The movement towards establishing legislated staffing levels for health care regimes is at its strongest in the U.S. After sustained lobbying by the Californian Nurses Association, California introduced comprehensive legislation in 1999[73] to establish minimum staffing levels in hospitals through the use of nurse to patient ratios to ensure quality patient care.[74] Reasons for the introduction of this legislation included California had one of the

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[72] U.S., Bill H.R. 791, *Safe Nursing and Patient Care Act of 2005*, 109th Cong., 2005.

[73] U.S., A.B. 394, *An Act to add Section 2725.3 to the Business and Professions Code, and to add Section 1276.4 to the Health and Safety Code, relating to health care*, 1999, Reg. Sess., Cal., 1999.

[74] Prior California law in 1976-1977 established nursing levels in acute hospitals requiring a minimum of one nurse per two patients in intensive care and coronary care units and that 50 percent of the nurses working these units be registered. Regulations from the 1990s require hospitals to develop and use patient

lowest nurse-to-patient ratios of any state in the U.S. (due to retrenchments caused by managed care and market based decisions) and studies linked the decline in nurse to patient ratios with an increase in the severity of the illnesses faced by patients. The ratios were implemented in stages, with the first stage being a 6:1 ratio in general medical-surgical units and moving to a 5:1 ratio in 2005. Programs could apply for a waiver to establish flexible staffing strategies or an exemption in the case of rural facilities.

In 2004, the Governor of California passed emergency regulations to suspend, for three years, the second stage of the program, while the Department of Health Services conducted a study of the effects of the law. He cited concerns from provider groups that hospitals would have to close or refuse to admit patients[75] if the new ratios were enforced. Provider groups were also concerned that the 6:1 ratio is actually the safe standard and that the state was trying to "raise the bar" by introducing the 5:1 ratio.[76] However, a Superior Court Judge in early March 2005 overturned the emergency regulations and ruled that California hospitals must comply with the newer, more stringent regulations.[77] The judge decided there was no emergency to justify use of such powers and that there was no substantial risk of harm if the ratio was lowered as scheduled.

The Californian legislation requires that the Department of Health Services establish minimum nurse-to-patient ratios for registered and licensed practical nurses in acute care hospitals, acute psychiatric hospitals and specialty hospitals. The legislation also prohibits unlicensed personal from performing certain procedures, including: the administration of medication; venipuncture; parental or tube feedings; inserting nasogastric tubes; inserting catheters; tracheal suctioning; assessment of patient condition; patient education; and moderate complexity laboratory tests. Enforcement of the ratios is weak – the Department inspects the hospital within two days if there is an immediate threat to the safety of patients and 70 days if it judges that there is no threat. If there is a violation the hospital must submit an action plan. The Department of Health Services has no power to impose fines or monetary penalties. Other mechanisms do exist. Medi-Cal (Medicaid) and Medicare require that hospitals comply with all laws and regulations and can audit and deny payment. It also increases an institution's medical malpractice risk if it is not in compliance with the law.

Legislation was also introduced in Hawaii, Tennessee, Missouri, and Iowa in 2004 requiring specific nurse-to-patient ratios in hospitals and/or other health care facilities. Connecticut legislation, introduced in 2004, calls for the Commissioner of Public Health to adopt regulations establishing minimum nurse-to-patient ratios. In 2004, Maine

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classification systems to measure the acuity of patients and determine nurse staffing needs for inpatient units on a shift-by-shift basis. Joanne Spetz, "California's Minimum Nurse-to-Patient Ratios: The First Few Months" (2004) 34:12 J. Nurs. Admin. 571.

[75] There are no reports of permanent reduced access to inpatient care from California directly attributable to the ratios, *Ibid.*

[76] Lynda Gledhill, "1-to-5 Nurse Patient Ratio Must be Met, Judge Says. Ruling on State's Hospitals is Upheld, Overriding Governor" *San Francisco Chronicle* (5 March 2004) B7.

[77] *Ibid.*

enacted legislation requiring minimum nurse to patient staffing ratios determined by a staffing system in which hospitals are required and held accountable for developing nurse staffing plans to respond to patient numbers and acuity and staff skill mix. Illinois, New York, Tennessee, Rhode Island, Pennsylvania, Michigan, and Massachusetts have introduced legislation requiring a combination of minimum nurse to patient ratios augmented by hospital based staffing systems.

Nurse-to-patient ratios are also on the agenda for Federal legislators in the U.S. The *Nurse Staffing Standards for Patient Safety and Quality Care Act 0f 2005*[78] is currently being considered by House committees.

Professional Regulation

The regulation of health practitioners occurs at the state level. All states require health practitioners to possess a license or certificate as a means of ensuring they are competent to practice.

Generally, state boards or professional bodies conduct licensing. These Boards in addition to controlling entry into the profession also protect the public by disciplining practitioners who are incompetent or who engage in unprofessional practice. Deriving their authority from state professional practice laws, some boards are independent self-regulatory bodies with full licensing and disciplinary powers, while others are part of larger state agencies, such as Departments of Health.

The Pew Health Professions Commission (a private research commission) noted in its work from 1989-1999 the conflict of interest in vesting professional boards with government authority. It suggested the development of an interdisciplinary oversight board to coordinate health professional regulation in each state.[79]

In Virginia, for example, a Board of Health Professions is established.[80] The Board is comprised of one member from each regulatory body and five members appointed by the governor. Its role as set out in statute is to:

> 1. To evaluate the need for coordination among the health regulatory boards and their staffs and report its findings and recommendations to the Director and the boards;
> 2. To evaluate all health care professions and occupations in the Commonwealth, including those regulated and those not regulated by other provisions of this title, to consider whether each such profession or occupation should be regulated and the degree of regulation to be imposed. Whenever the Board determines that the

[78] U.S., Bill H.R. 1222, To amend the Public Health Service Act to establish direct care registered nurse-to-patient staffing ratio requirements in hospitals, and for other purposes, 109th Cong., 2005.
[79] The Pew Health Professions Commission, online: Future Health <http://www.futurehealth.ucsf.edu/compubs.html>
[80] *Department of Health Professions*, Va. Code Ann. tit. 54.1 § 54.1-2500 (1988).

> public interest requires that a health care profession or occupation which is not regulated by law should be regulated, the Board shall recommend to the General Assembly a regulatory system to establish the appropriate degree of regulation;
> 3. To review and comment on the budget for the Department [Department of Health Professions];
> 4. To provide a means of citizen access to the Department;
> 5. To provide a means of publicizing the policies and programs of the Department in order to educate the public and elicit public support for Department activities;
> 6. To monitor the policies and activities of the Department, serve as a forum for resolving conflicts among the health regulatory boards and between the health regulatory boards and the Department and have access to departmental information;
> 7. To advise the Governor, the General Assembly and the Director on matters relating to the regulation or deregulation of health care professions and occupations;
> 8. To make bylaws for the government of the Board of Health Professions and the proper fulfillment of its duties under this chapter;
> 9. To promote the development of standards to evaluate the competency of the professions and occupations represented on the Board;
> 10. To review and comment, as it deems appropriate, on all regulations promulgated or proposed for issuance by the health regulatory boards under the auspices of the Department. At least one member of the relevant board shall be invited to be present during any comments by the Board on proposed board regulations;
> 11. To review periodically the investigatory, disciplinary and enforcement processes of the Department and the individual boards to ensure the protection of the public and the fair and equitable treatment of health professionals;
> 12. To examine scope of practice conflicts involving regulated and unregulated professions and advise the health regulatory boards and the General Assembly of the nature and degree of such conflicts;
> 13. To receive, review, and forward to the appropriate health regulatory board any departmental investigative reports relating to complaints of violations by practitioners of Chapter 24.1 (§ 54.1-2410 et seq.) of this subtitle;
> 14. To determine compliance with and violations of and grant exceptions to the prohibitions set forth in Chapter 24.1 of this subtitle; and
> 15. To take appropriate actions against entities, other than practitioners, for violations of Chapter 24.1 of this subtitle.[81]

The Department of Health Professions, receives all complaints about registered health professions and records them, monitors the operations of the state boards in response to complaints, assists them perform their functions, establishes a health professional intervention program and a prescription monitoring program. It also performs other functions. Beneath the Department, Boards of Medicine, Nursing and so on operate.[82]

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[81] *Ibid.*
[82] *Ibid.*

The Pew Commission also recommended the establishment of uniform complaint and disciplinary processes across the professions and between states and the use of consistent regulatory terminology and uniform standards for entry to practice. Montana is one of the states that has adopted the consistency recommendations of the Pew Commission when it adopted a uniform licensing Act for all professional and technical occupations[83] as has Virginia.

In the past, licensure bodies have attempted to ensure the initial competence of professional by enforcing education and examination requirements but have largely ignored the problem of ongoing competence.[84] Historically, licensure bodies have monitored ongoing competence through policing continuing education requirements and investigating complaints. Many states have in place continuing medical education (CME) requirements for physicians seeking re-licensure as a means of ensuring ongoing competence.[85] As part of the MCARE Act, physicians in Pennsylvania seeking biennial licensure renewal (for the period from Jan 1st, 2005 to Dec 31st, 2006) will be required to complete 100 hours of CME and at least 12 of those hours must be completed in activities concerning patient safety and risk management. The Board will conduct random audits to ensure compliance with the requirements and non-compliance may result in disciplinary action. Completion of continuing education credits focused on patient safety is also a condition of licensure in Florida.[86] Many question the effectiveness of continuing education mechanisms as a tool for ensuring quality and note that at best such programs help a professional to retain a more current knowledge base it certainly cannot assure competence.[87]

The responsibility for competence has therefore largely been borne by the disciplinary process. Professional regulation acts in all states set out quality related criteria such as incompetence as a ground for discipline. Acts may also authorize disciplinary actions for repeated malpractice or negligent conduct and for individual incidents of gross negligence. Some Acts also specify that certain acts are grounds for disciplinary action such as the use of steroids to enhance athletes' performance. Lastly, sanctions are available for physical or mental impairment, substance abuse etc. In order to invoke the disciplinary process boards must: identify professionals with disciplinary problems; investigate; prove incompetence; and respond with sanctions. Boards have primarily used patient complaints to identify problem practitioners. Although increasingly Boards may also conduct investigations on the basis of reports or referrals from other bodies, such as

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[83] *Uniform Professional Licensing and Regulatory Procedures*, Mont. Code Ann. tit. 37 § 37-1:301-19 (1995).

[84] Timothy S. Jost, "Oversight of the Competence of Healthcare Professionals," in T. Jost ed. *Regulation of the Health Professions* (Chicago: Health Administration Press, 1997).

[85] Federation of State Medical Boards, *Protecting the Public: How State Medical Boards Regulate and Discipline Physicians* online: FSMB <www.fsmb.org>. Critics of traditional continuing education (CE) note, that while it may help the professional have a more current knowledge base, that it does little to ensure professionals actually are practicing competently and studies have shown little relationship between traditional CE and actual quality of care. They argue competency evaluation should look at actual care processes and outcomes, rather than just general knowledge, and should be specific to the practitioner's area of practice. Jost, *supra* note 84.

[86] Fla. Stat. § 456.013 (2005).

[87] Jost, *supra* note 84 at 32.

malpractice insurers or hospitals that revoke privileges, and certain reports or referrals are mandatory under federal law and the laws of many states. Cited as a potential model for other states, the Massachusetts Board of Registration in Medicine conducts a clinical review of doctors who have made three or more malpractice payments.[88] Under Pennsylvania's 2002 *Medical Care Availability and Reduction of Error Act* (MCARE Act), physicians are required to self-report to the State Board of Medicine any civil malpractice claim brought against them within 60 days, as well as any controlled substance convictions and other serious criminal offenses.

Thus, the Boards enforce reactively rather than proactively. The focus is usually on whether the complaint is valid not whether the professional is competent. The Board may refer the matter for disciplinary action if it feels that it is warranted. Usually, disciplinary action is undertaken with the (reluctant in some cases) assistance of the state attorney general's office. Disciplinary action is long and expensive and so many boards resolve meritorious complaints though the use of consent agreements (settlements). Some states have mechanisms for informal dispute resolution systems aimed at resolving complaints at a low level. Consent agreements often do not address underlying competency problems and so may not protect the public.[89] If no consent agreement is reached, the Board may apply sanctions, the greatest of which, revocation, is not used often. Boards can also place conditions on practice and suspension. In general, Boards have increased the public's ability to access information following the trends towards more open disclosure. Some have gone even further and have practitioner data on the internet that includes disciplinary information and information about volumes and comparative success rates, for example in Massachusetts.[90]

Legislation in many jurisdictions allows reviews for mental, physical or competency assessment where there is reason to suspect incompetence and such reviews have been considered constitutional by the courts. Maryland for example has a peer review program, Virginia an intervention program and Ohio has a quality intervention program.

At the federal level, a National Practitioner Data Bank was established through the *Health Care Quality Improvement Act of 1986* (HCQIA). The legislation was enacted because Congress believed increasing occurrences of medical malpractice litigation and quality of care concerns required a national response. The database is intended to minimize the risk of incompetent physicians moving from state to state by providing a centralized information repository that permits bodies reviewing practitioner credentials to confirm practitioner supplied information. By law, malpractice insurers must report malpractice payments made as part of a settlement or a judgment to the database. State medical licensing boards, hospitals, managed care organizations and professional societies must report certain adverse actions taken for reasons related to professional competence or conduct. For example, hospitals are required to report any professional review action that adversely affects a physician's clinical privileges for longer than 30 days. The Act requires information to be reported on a least a monthly basis and contains

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[88] Robert Pear, "Panel Seeks Better Disciplining of Doctors" *The New York Times*, (5 January 2005).
[89] Jost, *supra* note 84 at 17.
[90] Online: MHQP< http://www.mhqp.org/default.asp?nav=010000>.

various sanctions for failing to report, with malpractice insurers facing fines of up to 10,000 dollars. Hospitals must query the databank when first granting clinical privileges to physicians and once every two years thereafter.

Overseen by the federal Department of Health and Human Services, the databank is required to provide information requested by state licensing boards and other health care entities that are in or may be considering an employment relationship with the physician. Physicians can self-query the databank. The information is otherwise confidential and it is not accessible by the public. Query fees fund costs associated with the databank.

A survey conducted by the Institute for Health Services Research and Policy Studies at the University of Illinois at Chicago indicated that the databank's information changed nearly 40,000 credentialing or licensing decisions each year.[91] The Office of the Inspector General estimates that information from the databank influences hospital and managed care organization credentialing decisions about two to three percent of the time.[92] Some point to these numbers as proof that the databank has a minimal effect and argue that it should be abolished; others suggest that two percent could involve the identification of hundreds or even thousands of practitioners who in the course of practice could endanger thousands of patients.[93] However, the system suffers from underreporting and a lack of timely reporting, and federal officials acknowledge that no fine or penalties have ever been imposed for non-compliance.[94] Other loopholes that allow a physician to avoid being reported include the requirement that only physicians named in final settlements are reportable. In these cases, physicians may not agree to a settlement until their names are removed. Some patient safety advocates say that the databank should be abolished and replaced with a different system that investigates both organizations and individuals, as the databank's focus on malpractice claims settled by individual physicians "perpetuates blame and holds systems-thinking back."[95]

Another federal initiative is a drug utilization review (DUR) scheme. The Department of Health, Education and Welfare issued regulations in 1974 requiring monthly review of prescription drug regimens for Medicaid patients in skilled nursing facilities. In 1990 Congress strengthened the requirements for DUR in Medicaid programs requiring that by 1993 states were to establish DUR programs for covered outpatient drugs "in order to assure that prescriptions (1) are appropriate, (2) are medically necessary, and (3) are not likely to result in adverse events".[96] So states were to implement programs containing

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[91] Christopher Conover & Emily P. Zeitler, *National Practitioner Databank: Health Facilities Regulation*, (Working Paper No. P 5) (Durham, N.C.: Duke University Center for Health Policy, Law and Management, 2004); online at: <www.hpolicy.duke.edu>.

[92] Mark Yessian & Joyce Greenleaf, "The Ebb and Flow of Federal Initiatives to Regulate Healthcare Professionals" in T. Jost ed. *Regulation of the Healthcare Professions* (Chicago: Health Administration Press, 1997) at 182.

[93] *Ibid.*.

[94] Cheryl W. Thompson, "Poor Performance Records are Easily Outdistanced" *Washington Post* (12 April 2005) A01.

[95] Martin J. Hatlie & Susan Sheridan, "The Medical Liability Crisis of 2003: Must We Squander the Chance to Put Patients First?" (2003) 22:4 Health Aff. 37.

[96] 42 U.S.C. § 1396r-8 (2005).

prospective drug review, retrospective drug use review, and educational outreach. However, the chief impetus for the changes was cost containment. The federal government requires the states to submit annual reports but does not more than that to oversee the program. Most states have established prospective systems such as statewide online DUR systems that require submission of Medicaid claims online at point of sale. Claims are then screened against set criteria and payment may be disallowed or an explanation demanded if it does not meet those standards. They have also established retrospective systems of prescription review; physicians who do not comply with the standards are sent an educational letter. A review team assembled by the American Pharmaceutical Association found that "assessments of the impact on quality of care were limited to anecdotal evidence".[97]

Products Regulation

The Food and Drug Administration (FDA) is the federal agency responsible for ensuring the safety, effectiveness and quality of drugs, biological products, and medical devices available for use in the United States. The agency regulates medical products using a risk management framework aimed at maximizing the benefits and minimizing the risks of medical product use for the American public. [98] As part of the Department of Health and Human Services, FDA carries out a wide range of regulatory activities in order to protect consumers, such as:

1) assessing the safety and effectiveness of products before they are permitted to enter the market (pre-market review);
2) monitoring the safety and efficacy of products once they enter the market (post-market surveillance);
3) setting standards for the labeling, packaging and manufacturing of medical products.

The *Federal Food, Drug, and Cosmetic Act of 1938*, as amended, gives FDA the authority to establish and enforce regulations governing medical products. The Act, its amendments and regulations contain provisions that outline new product approval requirements, post-marketing reporting rules and manufacturing standards for medical products.

Pre-marketing Surveillance

Most agency resources are devoted to pre-marketing surveillance. All drugs and devices must gain approval before they can be marketed and that approval also relates to the

[97] E.E. Lipowski & T. Collins, *Medicaid DUR Programs 1993* (Washington D.C.: American Pharmaceutical Association Foundation, 1995).
[98] U.S. Food and Drug Adminstration, *Managing the Risks from Medical Product Use: Creating a Risk Management Framework*: (Rockville, MD: Food and Drug Adminstration, 1999) at 21, online: <http://www.fda.gov/oc/tfrm/riskmanagement.html>.

proposed use for the drug. The FDA conducts assessments of the safety and effectiveness of drugs. However, it uses and analyses data provided to it by the drug's manufacturer, gained through laboratory and clinical trials. It also ensures that it is safe to conduct clinical trials on human volunteers with newly developed drugs.

The FDA has recently been the subject of sustained criticism over the way it undertakes surveillance of the pre-marketing safety of drugs and devices. Since the adoption in 1992 of the *Prescription Drug User Fee Act*, which allowed the FDA to charge "user fees" median approval times for standard drugs decreased from 27 months in 1993 to 14 months in 2001, but as a consequence, drug recalls increased from 1.56% for 1993-1996 to 5.35% for 1997-2001.

There was also a cultural change within the FDA which placed a premium on getting drugs approved quickly and placed pressure on staff to complete evaluations. Rates of approval for new drugs became part of employees' performance evaluation. Employees who raised concerns about the safety of drugs were said to be systematically suppressed. When concerned were noted about possible serious side-effects approvals were still given for a number of drugs, many of which subsequently were withdrawn from the market.[99]

In addition, an investigation of 18 FDA expert advisory panels revealed that more than half of the members of these panels had direct financial interests in the drug or topic they were evaluating and for which they were making recommendations.[100]

Post-Marketing Surveillance

Medwatch is the FDA Safety Information and Adverse Event Reporting Program. It administers voluntary and mandatory adverse event reporting programs in relation to drugs, biologics and devices.

The Medical Device Reporting (MDR) Regulation allows FDA to identify and monitor significant adverse events involving medical devices.[101] It establishes mandatory reporting requirements for manufacturers, importers, and user facilities (i.e. nursing homes and hospitals) in relation deaths and serious injuries attributable to device use. The MAUDE (Manufacturer User Facility and Distributor Experience) is a searchable on-line database contains data from both mandatory reports and voluntary reports submitted by consumers and health professionals.

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[99] Diedtra Henderson and Christopher Rowland, Once 'Too Slow,' FDA Approvals Called 'Too Fast'" *Boston Globe* (10 April 2005), online: Boston Globe <http://www.boston.com/business/articles/2005/04/10/fda_criticized_as_too_quick_to_ok_drugs/>.

[100] Phil B. Fontanarosa, Drummond Rennie & Catherine D. DeAngelis, "Postmarketing Surveillance—Lack of Vigilance, Lack of Trust" (2004) 292:21 JAMA 2647 and D. Cauchon "FDA Advisers Tied to Industry" *USA Today* (25 September 2000) A1.

[101] 21 C.F.R. § 803 (2002).

A separate database for drug related adverse events, entitled AERS (Adverse Event Reporting System), receives reports from drug manufacturers as required by regulation. Mandatory reporting is required for drugs and biologics for:

- adverse drug experiences on marketed prescription drugs for human use without approved new drug applications[102]
- investigational new drug applications[103]
- post-marketing surveillance[104]

In respect of serious adverse events, manufacturers have 15 days to report to the FDA.

Together with the CDC, the FDA sponsors the VAERS reporting system, a national vaccine safety program that receives reports of adverse events relating to vaccine use. The *National Childhood Vaccine Injury Act* requires health care providers to report adverse events that may be associated with vaccines.[105] However, patients and families can report voluntarily. It is difficult often to establish causation in regard to vaccine related injuries because technical data required to conduct analyses is often omitted from reports.[106]

Medwatch also provides a forum for both healthcare professionals and the public to report voluntarily serious adverse events, product quality problems, or product use errors associated with the use of drugs, devices, biologics, or dietary supplements regulated by the FDA. It is an online system. As part of its role, it provides important and timely clinical information about safety issues involving medical products, including prescription and over-the-counter drugs, biologics, medical and radiation-emitting devices, and special nutritional products (e.g., medical foods, dietary supplements, and infant formulas).[107]

Information from these programs is analysed, the FDA issues public safety alerts, and, in some cases, the FDA may recall products.

The FDA's post-market surveillance system has been the subject of profound criticism. Critics note its reliance on voluntary reporting, the poor quality of reports with little detail and poor documentation, underreporting of adverse events, difficulty in calculating adverse event rates, limited ability to establish causal relationships and difficulty in determining whether the adverse event related to the drug or the disease the drug was to treat.[108]

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[102] 21 C.F.R. § 310.305 (2002).
[103] 21 C.F.R. § 312.32 (2002).
[104] 21 C.F.R. § 314.80 (2004).
[105] *National Childhood Vaccine Injury Act of 1986*, codified as *Public Health Service Act* §2111, et seq., 42 USC § 300aa-11 et seq (1986).
[106] Centers for Disease Control, "Overview of Vaccine Safety" National Immunization Program <http://www.cdc.gov/nip/vacsafe/>
[107] Medwatch, online: FDA <http://www.fda.gov/medwatch/What.htm>.
[108] Fontanarosa, et al. *supra* note 100.

Critics suggest that the major problem with the current system is that drug manufacturers are largely responsible for collecting, evaluating, and reporting data from post-marketing studies of their own products. This is problematic in a number of ways. It appears that fewer than half of the post-marketing studies that manufacturers have made commitments to undertake as a condition of approval have been completed and many have not even been initiated. Despite the mandatory adverse event reporting system for companies subject to the FDA's post-marketing safety reporting regulations, drug manufacturers may be tempted to conceal available data that may signal the possibility of major risks. In some cases, the FDA and drug manufacturers may fail to act on that information and fail to conduct appropriate studies to examine a potential risk rigorously and promptly.[109] In some cases, serious adverse drug events are quite uncommon, and detecting them accurately and using them to determine incidence rates can be difficult with the reactive voluntary reporting systems for adverse drug events. Some companies may neglect to acknowledge reports that indicate harm and fail to initiate proper studies to determine risk. Companies may be well aware of analyses of serious adverse drug event data but may fail to report them or report them in a less than timely manner. Pharmaceutical companies may a number of tactics to protect their interests and prevent the release of information damaging to the interests of their products.[110]

In response to the sustained criticism, the FDA announced in 2005 that it is taking measures to strengthen the safety program for marketed drugs. It is sponsoring an IOM study of the drug safety system, implementing a program to adjudicate differences of opinion between FDA staff and outside experts, appoint a director of drug safety (position had been vacant for 13 months), conduct drug safety and risk assessment consultations and public risks assessment guidelines. It has also created a Drug Safety Oversight Board (DSB) to oversee the management of drug safety issues. The DSB will oversee the management of important drug safety issues within the Center for Drug Evaluation and Research (CDER). The DSB will comprise members from the FDA and medical experts from other HHS agencies and government departments (e.g., Department of Veterans Affairs) who will be appointed by the FDA Commissioner.[111]

Monitoring

The FDA monitors compliance with the regulations through an inspections process. The FDA can issue warning letters if inspection demonstrates that there are significant deviations or violations from the regulatory requirements. If there are a pattern of violations that are not remedied then injunction, citation or prosecution can be considered.[112]

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[109] *Ibid.*
[110] *Ibid.*
[111] Food and Drug Administration, Press Release "Improvements in Drug Safety Monitoring" (15 February, 2005).
[112] U.S., FDA, *Enforcement of the Postmarketing Adverse Drug Reactions Reporting Regulations* online: FDA <http://www.fda.gov/cder/aers/chapter53.htm>.

Medication Errors

Since 1992, the FDA receives and monitors reports on medical errors associated with medication use from the United States Pharmacopeia (USP) and the Institute for Safe Medication Practices (ISMP). It also reviews Medwatch reports for possible medication errors. The Center for Drug Evaluation and Research's Medication Error Prevention Program analyses data to provide feedback to others at the FDA and to provide warnings and education to providers and the public about medication errors.[113]

Inquiry Processes

Death investigations in the U.S. are undertaken by Coroners and/or Medical Examiners depending on the jurisdiction. Approximately, 10 states have coronial systems, 25 have medical examiners and 18 have mixed systems. Around 25 percent of the U.S. population is serviced by state controlled systems, while the remaining 75 percent are serviced by a patchwork of regional, county, or city based systems for death investigation.[114]

In 1986, responding to concerns that there was a lack of uniformity in death investigation policies, poor communication between jurisdictions, and that there needed to be a mechanism to disseminate death investigation data, the Centers for Disease Control and Prevention (CDC) established the Medical Examiner and Coroner Information Sharing Program (MECISP). Funding for this program was terminated in 2004. The goals of the MECISP were to:

- To improve the quality of death investigations in the United States and to promote the use of more standardized policies for when and how to conduct these investigations.
- To facilitate communication among death investigators, the public health community, federal agencies, and other interested groups.
- To improve the quality, completeness, management, and dissemination of information on investigated deaths.
- To promote the sharing and use of Medical Examiner and Coroner death investigation data.[115]

The MECISP, amongst other things:

- Developed model death investigation forms and file structures.

[113] See Center for Drug Evaluation and Research website at <http://www.fda.gov/CDER/drug/MedErrors/default.htm

[114] Centers for Disease Control, "Death Investigation Summaries," online: <http://www.cdc.gov/epo/dphsi/mecisp/summaries.htm>.

[115] Centers for Disease Control, "About MECISP," online:<www.cdc.gov/epo/dphsi/mecisp/about.htm>.

- Developed model formats for annual and statistical death investigation reports. The reports were then distributed to and used by ME/C offices.
- Collaborated with medical examiners, coroners, public health researchers, and others in epidemiologic studies of deaths routinely investigated by ME/C offices.
- Conducted studies to identify problems associated with methods of collecting death investigation and mortality data.
- Consulted with ME/C offices to help establish computerized data systems. [116]

In 2003 the NIH convened a Workshop on the Medicolegal Death Investigation System that focused on "the role of the medical examiner/coroner death investigation system and its promise for improving: the criminal justice system; health and medical care; public health surveillance; epidemiologic research; prevention programs; and response to bioterrorism."[117] Some of the conclusions were that the ability for coroners/medical examiners to contribute to these areas, especially health and medical care, was limited due to variability in the statutory criteria for coronial review (with only some requiring review of deaths relating to medical quality of care issues), variability in the scope, extent, and quality of individual investigations, variability in the extent of examination and the quality of the evidence produced, and variations in the types of deaths investigated,[118] thus indicating that the CDC initiative had not resulted in significant change.

In New York State, for example, the mixed coronial/medical examiner system investigates deaths:[119]

- By violence, whether criminal violence, suicide or casualty.
- Caused by unlawful act or criminal neglect.
- Occurring in a suspicious, unusual, or unexplained manner.
- Caused by suspected criminal abortion.
- While unattended by a physician, so far as can be discovered, or where no physician is able to certify the cause of death as provided in public health law and in form as prescribed by the Commissioner of Health can be found.
- Of a person confined in a public institution other than a hospital, infirmary or nursing home.
- Death occurring to an inmate of a correctional facility.

In Massachusetts the following deaths must be reported to the Coroner:[120]

- death where criminal violence appears to have taken place, regardless of the time interval between the incident and death, and regardless of whether such violence appears to have been the immediate cause of death, or a contributory factor;

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[116] *Ibid.*
[117] National Institutes of Health, *Workshop on the Medicolegal Death Investigation System* (2003) online: NIH <http://www.iom.edu/event.asp?id=6360>.
[118] R. Hanzlick, "The Medicolegal Death Investigations Systems in the U.S." presented to National Institutes of Health, *Workshop on the Medicolegal Death Investigation System* (2003) online: NIH <http://www.iom.edu/event.asp?id=6360>.
[119] NYCL § 673.
[120] Mass. Gen. Laws Ann. ch. 38 § 1 et seq.

- death by accident or unintentional injury, regardless of time interval between the incident and death, and regardless of whether such injury appears to have been the immediate cause of death, or a contributory factor;
- suicide, regardless of the time interval between the incident and death;
- death under suspicious or unusual circumstances;
- death following an unlawful abortion;
- death related to occupational illness or injury;
- death in custody, in any jail or correctional facility, or in any mental health or mental retardation institution;
- death where suspicion of abuse of a child, family or household member, elder person or disabled person exists;
- death due to poison or acute or chronic use of drugs or alcohol;
- skeletal remains;
- death associated with diagnostic or therapeutic procedures;
- sudden death when the decedent was in apparent good health;
- death within twenty-four hours of admission to a hospital or nursing home;
- death in any public or private conveyance;
- fetal death, as defined by section two hundred and two of chapter one hundred and eleven, where the period of gestation has been twenty weeks or more, or where fetal weight is three hundred and fifty grams or more;
- death of children under the age of 18 years from any cause;
- any person found dead;
- death in any emergency treatment facility, medical walk-in center, day care center, or under foster care; or
- deaths occurring under such other circumstances.

The medical examiner may choose whether to undertake an examination in Massachusetts.

There appears to be no national repository of coroner or medical examiner reports and no central database to track deaths related to medical error.[121]

Public inquiries seem to be a tool of limited use in the United States. Senate and congressional committees at the federal and state level can convene public inquiries through the Committee review process. At the federal level, a national commission of inquiry can also be convened if Congress introduces legislation for its creation. For instance, Congress introduced a bill to establish a commission looking into the disaster response on Sept. 8th after Hurricane Katrina.

[121] Further information (last updated in 2004) about the structures surrounding Coroner and Medical Examiners jurisdiction for all U.S. states and Canadian provinces is available at: Centers for Disease Control, "Death Investigation System Description," online: <www.cdc.gov/epo/dphsi/mecisp/death_investigation.htm>.

Compensation Systems

Medical malpractice claims in the United States are addressed through the common law tort system. Limited exceptions include a federal no fault compensation program for injuries caused from children's vaccines and no fault compensation programs for certain severe injuries to newborns in Florida and Virginia.[122] Traditionally, tort law has primarily been a subject of state, rather than federal, authority.[123] During the past 30 years, states have increasingly enacted legislation modifying common law tort rules and establishing other tort reform measures in response to medical indemnity crises.[124] These tort reforms have primarily focused on controlling the frequency and costs of litigation using measures such as damage caps rather than reducing medical error.[125] The United States appears to be emerging from a medical indemnity crisis in the early 2000s that saw major physician insurers exit the market and dramatic increases in liability premiums in many states.[126]

Since the release of the IOM report *To Err is Human* in 2000, increased attention focused on how the current US medical liability system affects patient safety.[127] In terms of the deterrence function of tort law, the few existing analyses provide "very limited evidence that providers who experience malpractice claims have fewer adverse events and instances of negligence in the future."[128] Other shortcomings of the system are that only a small percentage of patients who are injured because of negligence pursue a claim and even fewer receive compensation, while studies have shown a large portion of malpractice claims do not involve a negligent injury.[129] Injury prevention in the tort system has been described as "piecemeal rather than systematic" and annual costs of medical liability litigation and defensive medicine have been estimated at 28 billion.[130]

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[122] Randall R. Bovberg & Laurence R. Tancredi, "Liability Reform Should Make Patients Safer: 'Avoidable classes of Events' are a Key Improvement" (2005) 33:3 J.L. Med. & Ethics 478.

[123] Peter Budetti & Teresa M. Waters, *Medical Malpractice Law in the United States* (Menlo Park, CA: The Kaiser Family Foundation 2005) at 1.

[124] *Ibid.* at 4. Common tort reforms include caps on non-economic damages, abolishing joint and several liability and allowing periodic payment of damages. Mimi Marchev, *The Medical Malpractice Insurance Crisis: Opportunity for State Action* (Portland, ME: National Academy for State Health Policy, 2002) at 9-12.

[125] *Ibid.* at 2, 9 & 18.

[126] M. Mello, C. Kelly & T. Brennan, "Fostering Rational Regulation of Patient Safety" (2005) 30:3 J. Health Pol. 375 at 389. Bovberg & Tancredi *supra* note 122 at 478.

[127] Joint Commission on Accreditation of Healthcare Organizations, *Healthcare at the Crossroads: Strategies for improving the medical liability system and preventing patient injury* (Wash., D.C.: JCAHO, 2005); Mimi Marchev, Medical Malpractice and Medical Error Disclosure: Balancing facts and fears (Portland, ME.: National Academy for State Health Policy, December 2003); T. Brennan & M. Mello, "Patient Safety and Medical Malpractice: A Case Study" 2003 139:4 Ann. Int. Med. 267.

[128] Mello *et al supra* note 126 at 389. Scholars concluded that it was impossible to determine whether the medical malpractice system "actually stimulates cost justified injury prevention" from the existing data. However, the evidence suggests a positive cost-benefit impact on practices around physician-patient discussion of treatment risks and institutional injury prevention programs. Don Dewes *et al.* "Medical Accidents" in D. Dewes, D. Duff, M. Tribelcock, eds., *Exploring the Domain of Accident Law: Taking the Facts Seriously*, (New York: Oxford University Press, 1996) at 112.

[129] JCAHO, *supra* at note 127 at 13. Mello *et al*., *supra* note 126 at 388.

[130] Bovberg & Tancredi *supra* note 122; JCAHO, *supra* note 127 at 4.

The current tort system has been seen as working against patient safety on another front, as fear of litigation keeps providers from sharing information needed for patient safety improvements and has been cited as a factor in the underreporting of adverse events.[131]

To address its medical malpractice crisis, the state of Pennsylvania passed in 2002 the *MCARE Act*, which contained patient safety, tort law and insurance reforms. Under the Act, hospitals and other facilities are required to report all adverse events and near miss incidents to an independent non-regulatory state agency. The Act also requires facilities to provide written notification of an adverse event to the affected patient within seven days. This notification does not constitute an admission of liability. A number of states have also passed laws that protect provider apologies from being used in court.[132]

At the federal level, the *Fair and Reliable Medical Justice Act* Bill was introduced in June 2005 in the Senate. The act aims to "restore fairness and reliability to the medical justice system and promote patient safety by fostering alternatives to current medical tort litigation, and for other purposes."[133] The bill would allow the federal government to fund state based demonstration projects of alternatives to the current tort systems. States seeking a federal grant would have to demonstrate how their project will foster prompt and fair resolution of disputes, the early disclosure of health care errors, enhanced patient safety and access to liability insurance. A State will be deemed to meet the criteria if they choose from one of the models already described in the Act, which include an early disclosure and compensation model, an administrative determination of compensation model and a special health court model.

The *National Childhood Vaccine Injury Act* of 1986 created a no fault compensation program for injuries arising from children's vaccinations in response to concerns that tort liability was causing drug manufacturers to stop producing vaccines. Claimants receive automatic compensation if their injury is listed in the Vaccine Injury Table. If their injury is not listed, they may also qualify for compensation if they can prove that a vaccine caused their condition or significantly aggravated a pre-existing condition. There are time limits for making a claim under the program. Eligible claimants are compensated up to $250,000 for death and in the case of injuries, they receive payment for all past and future otherwise uncovered medical expenses, nursing home or custodial care, loss of earnings, reasonable legal costs and up to $250,000 for pain and suffering. A federal court special master resolves disputes and decisions can be appealed. Rejected claimants or claimants who refuse the offered compensation may only sue in federal court. The program is believed to have encouraged safer vaccines, stabilized the vaccine market and provided a less adversarial and more efficient system of compensation. However, one study found pertussis vaccine claim results to be inconsistent with epidemiological knowledge. [134]

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[131] Bovberg & Tancredi. *supra* note 122 at 478; JCAHO, *supra* note 127 at 4; Marchev, *supra* note 127 at 2.
[132] JCAHO, *supra* note 127 at 11.
[133] U.S., Bill S. 1337, *Fair and Reliable Medical Justice Act,* 109th Cong., 2005.
[134] Bovberg & Tancredi, *supra* note 122 at 478.

In the late 1980's, both Virginia and Florida enacted legislation that created a no fault compensation program covering children who experienced severe neurological injuries at birth.[135] To be eligible, the child's injury must meet the legislative definition of "birth-related neurological injury."[136] In both states, eligible infants are those who suffered brain or spinal cord injury due to oxygen deprivation or mechanical injury. In Florida, these injuries must have resulted in permanent and substantial mental and physical impairment, while in Virginia, injuries that permanently disable motor function, result in developmental or cognitive disabilities, and necessitate permanent assistance for all activities of daily living are covered. Eligibility decisions in Florida are made by an administrative law judge and in Virginia, they are made by the Worker's Compensation commission. Coverage includes all reasonable and necessary medical, hospital, custodial care, residential, rehabilitative, special equipment and related travel expenses not already covered by other programs or private insurance. In Virginia, families also receive compensation for the child's lost earnings, while in Florida, they can receive an award of up to $100,000 dollars. Rights and remedies under the programs are exclusive and eligible families are not entitled to compensation through the tort system, unless there is clear and convincing evidence of intentional or willful harm and the civil suit is filed before the payment of an award under the program. The compensation funds are maintained through annual assessment payments from physicians and hospitals.

An evaluation of the programs after eight years of operation found administrative costs were very low compared to the tort system, and compensation and parental satisfaction was similar under the two systems. The number of claims was less than expected, which helped in preventing cost overruns but made the programs too small to conduct patient safety analysis.[137] An academic study of Florida's system published in 2000 found that in its first ten years, it provided relatively efficient, equitable and generous compensation to nearly 100 infants. However, it concluded that NICA's compensation role was at best a modest one, as almost the same number of severe birth-related injuries received malpractice awards of $250,000 or more during the program's operation as in the period prior to its establishment.[138]

Other Patient Complaint Mechanisms

Health care complaint mechanisms exist at the federal, state and institutional level. Section 1154(a) (14) of the *Social Security Act* requires quality improvement

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[135] *Virginia Birth-Related Neurological Injury Compensation Act*, Va. Code Ann. §§ 38.2-5000 to 38.2-5021; Va STAT 2-5000 to 5021); the statutory basis for Florida's Birth-Related Neurological Injury Compensation Plan, Fla. Stat. §§ 766.303-766.316 (2004). Florida's program is modeled after Virginia's. George Coppolo and Saul Spiegel, "Medical Malpractice No fault systems," OLR Research Report (December 8, 2003).

[136] Additional conditions apply. In Florida, obstetrical services must have been given in a hospital by a physician who participates in the program, while in Virginia, the infant must have been delivered in hospital by a participating physician or in a participating hospital. Participation by physicians and hospitals is voluntary.

[137] Bovberg & Tancredi, *supra* note 122 at 478.

[138] Coppolo and Speigel, *supra* note 135.

organizations to review all written complaints from Medicare beneficiaries that allege the quality of the covered services received did not meet professionally recognized standards of health care.

Adverse Event Reporting Systems

Adverse event reporting systems exist at the national and state level. Legislative debate and action in this area has been influenced by the recommendations of the 2000 IOM report *To Err is Human*. The report recommended the establishment of a nation wide mandatory reporting system supported by federal legislation, which would legally obligate health care institutions to report a defined list of adverse events resulting in serious harm or death in a standardized format. [139] This data would be collected by state governments, who would analyze reports and take follow up action. This system's primary purpose would be to hold providers accountable for improvements. Separate voluntary reporting systems would be encouraged in the health care industry to complement the mandatory reporting system and would be afforded legal protections.[140] Voluntary systems would focus on less serious adverse events and near miss incidents and data would be used to identify emerging concerns and patient safety improvement strategies.

National Level Adverse Event Reporting Systems

Since the release of the report, numerous pieces of proposed legislation meant to encourage medical error reporting have been introduced at the federal level in Congress.[141] The federal *Patient Safety and Quality Improvement Act of 2005* became law on July 29, 2005 and "reflects difficult negotiations and many compromises over almost five years of consideration."[142] The Act aims "to reduce the incidence of events that adversely effect patient safety" by creating a confidential voluntary reporting

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[139] IOM, *To Err supra* note 19 at 87, 88 & 104.
[140] *Ibid.*
[141] They include: U.S., Bill H.R. 3672, *Medical Error Prevention Act of 2000*, 107th Cong., 2000*;* U.S. Bill H.R. 5404, *Medicare Comprehensive Quality of Care and Safety Act of 2000*, 106th Cong. 2000*;* U.S. Bill S. 2038, *Medical Error Reduction Act of 2000*, 106th Cong., 2nd Sess. 2000; U.S. Bill S. 2378 *Stop All Frequent Errors (SAFE) in Medicare and Medicaid Act*, 106th Cong. 2nd Sess. 2000; U.S. Bill S. 2738, *Patient Safety and Errors Reduction Act*, 106th Cong. 2nd Sess., 2000; U.S. Bill S. 2743, *Voluntary Error Reduction and Improvement in Patient Safety Act*, 106th Cong. 2nd Sess., 2000; U.S. Bill S. 720, 108th Cong. 2003; U.S. Bill H.R. *663*, *Patient Safety and Quality Improvement Act*, 108th Cong. 2003.
[142] *Patient Safety and Quality Improvement Act of 2005*, Pub. L. No. 109-41, 119 Stat. 424 (codified at amended at 42 U.S.C. 299 et seq. (2005)). It is identical to the Bill H. 3205, *Patient Safety and Quality Improvement Act of* 2005, 109th Cong. 2005. Senator Jeffords, (I-VT), "P The Patient Safety and Quality Improvement Act of 2005" *Congressional Record-Senate p.* S8744, (July 22, 2005), Senator Jeffords sponsored the legislation.

system.[143] The legislation provides a framework in which health care providers and hospitals can report information on medical errors and near miss incidents to patient safety organizations (PSOs). Certified by the Secretary of the federal Department of Health and Human Services, a PSO is a public or private entity that performs the following activities:

(a) efforts to improve patient safety and the quality of health care delivery,
(b) the collection and analysis of patient safety work product[144]
(c) The development and dissemination of information to providers with respect to improving patient safety, such as recommendations, protocols or information regarding best practices
(d) the utilization of patient safety work product for the purposes of encouraging a culture of safety and of providing feedback and assistance to effectively minimize patient risk,
(e) the maintenance of procedures to preserve confidentiality with respect to patient safety work product
(f) the provision of appropriate security measures with respect to patient safety work product
(g) the utilization of qualified staff (including licensed medical professionals)
(h) activities related to the operation of a patient safety evaluation system and to the provision of feedback to participants in a patient safety evaluation system.[145]

Known as "patient safety work product," information created specifically for patient safety reporting purposes by providers or by PSOs while conducting the above activities is protected by confidentiality and evidentiary privilege provisions that seek to encourage voluntary reporting and information sharing while protecting access to other separate health information.[146] These legislative protections are meant to address barriers to open communication, such as the fear of malpractice litigation, and reflect "the belief that a culture of patient safety can flourish best in an environment where information, data, processes and recommendations enjoy legal protection and privilege."[147] By setting limits

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[143] Preamble, *Patient Safety and Quality Improvement Act of 2005*. J. Jeffords, Press Release "Sen. Jeffords' Patient Safety Bill passes House, Heads to President," (27 July 2005) online: <http://jeffords.senate.gov/~jeffords/press/05/07/072705patientsafety.html>

[144] Patient safety work product is defined in Section 921 (7) as any data, reports, records, memoranda, analyses (such as root cause analyses), or written or oral statements which are developed or assembled by a provider for reporting to a PSO and are reported to a PSO; or are developed by a PSO for the conduct of its patient safety activities, which could result in improved patient safety or identify/constitute parts of a patient safety evaluation system. It does not include a patient's medical record, billing and discharge information, other original patient or provider records or information that is collected, maintained or developed separately from a patient safety evaluation system.

[145] *Public Health Service Act* § 921(4)(5), 42 U.S.C. as amended by the *Patient Safety and Quality Improvement Act of 2005*, *supra* note 142. Additional criteria for certification as a patient safety organization is listed in Section 924 (b) (1), such as the primary function of the entity is to conduct activities to improve patient safety, the entity must have bona fide contracts with more than 1 provider and fully disclose any lack of independence from providers it contracts with, the entity is not a component of a health insurance issuer and the entity collects patient safety work product from providers in a standardized manner to allow for comparisons with other providers to the extent practical.

[146] *Ibid.*. §§ 921 (7) and 922.

[147] Jeffords, *supra* note 142.

on what is to be considered confidential and privileged, the legislation seeks to strike a balance with the need to access certain information in order to seek legal redress.

Privileged patient safety work product is not admissible into evidence or subject to subpoena or discovery in any civil, criminal or administrative matter at the federal, state or local level.[148] The privilege also applies to the federal *Freedom of Information Act* and similar federal, state or local legislation, as well as professional disciplinary proceedings.[149] There are three exceptions from both the privilege and confidentiality protections:

- disclosure for use in a criminal proceeding only if a court in camera determines that the data contains evidence of a criminal act, is material and cannot be found elsewhere;
- disclosure for use to extent required when an employee is bringing a civil action against a provider who took adverse employment action against them for reporting;
- disclosure of identifiable patient safety work product authorized by the identified providers.[150]

Additional exceptions from confidentiality include disclosures for patient safety activities, for accreditation purposes when given voluntarily by the provider and of non identifiable patient safety work product.[151] Privilege protections do not apply to voluntary disclosures of non identifiable patient safety work product.[152] These legislative protections are not to be interpreted as altering or preempting a provider's reporting requirements (of non patient safety work product) under State law or to the FDA. [153]

The Act also contains other protections. An accrediting body is unable to require a provider to reveal its communications with PSOs and is not permitted to take accrediting action against a provider based on the provider's good faith participation in the collection, development, reporting or maintenance of patient safety work product.[154] A provider may not take 'adverse employment action' against an employee if he or she in good faith reports information to the provider or a patient safety organization and the employee has the right to bring a civil action against the employer for violations of this section.[155]

The Act also requires the Secretary for Health and Human Services to maintain a network of patient safety databases to act as "interactive evidence-based management resource for providers, patient safety organizations and other entities."[156] The network of databases must have the capacity to accept, aggregate, and analyze non-identifiable patient safety

[148] *Supra* note 145 at § 922(a).
[149] *Ibid.*
[150] *Ibid.* at § 922 (c)(1).
[151] *Ibid.* at § 922 (c)(2).
[152] *Ibid.* at § 922 (c)(3).
[153] *Ibid.* at § 922 (g) (5) and (6).
[154] *Ibid.* at § 922 (d) (4) (B).
[155] *Ibid.* at § 922 (e).
[156] *Ibid.* at § 923(a).

work product voluntarily reported by these groups. This information will be used to analyze national and regional statistics, including trends in medical error, and the results are to be made available to the public and to appear in annual quality of care reports.[157] The Secretary may determine common data standards, reporting formats, and a standardized computer interface for information maintained in the network of patient safety databases.[158] Within 18 months after the network is operational, the Secretary must prepare a draft report concerning effective strategies for reducing medical errors and measures to encourage their use, which shall be submitted to the Institute of Medicine and made available to the public.[159] A final report must be submitted to Congress within 30 months of network's operation. The law is expected to cost 58 million over a four year period (2006-2010) and a report by the US Comptroller General on its effectiveness is to be submitted no later than February 1, 2010.[160]

The JCAHO and VA systems described below are not legislatively created, however, they are often referred to in the literature as systems of significance. The Department of Veteran's Affairs has both an internal and external reporting system for medical errors. Established in 1999 by the VA, the National Centre for Patient Safety promotes a systems approach to patient safety in all VA hospitals in the U.S. The Center developed an internal, confidential, non-punitive reporting and analysis system for adverse events, sentinel events and close calls. Multi-disciplinary teams conduct root cause analysis (RCA) of reported events, depending on the event's level of risk, and suggest strategies for systems improvement. Feedback is given to reporters and reports and RCAs are confidential. Information is collected in the Patient Safety Information System (PSIS). The system itself is not blame free. Those who undertake activities that are intentionally unsafe i.e. a criminal act, related to alcohol or substance abuse, are held to account, as these reported events are sent to the facility's director. Since its implementation, the NCPS has seen a 900 increase in close call reporting and a 30-fold increase in adverse event reporting.[161] In 2000, the VA developed a Patient Safety Reporting System (PSRS) in conjunction with NASA. This system is modeled on NASA's Aviation Safety Reporting System (ASRS), which since its creation in 1975 has been noted for its contributions to improving aviation safety.[162] PSRS is a voluntary, external, non-punitive reporting system available to all VA employees. Employees can confidentially report adverse events or close calls. NASA receives the data, de-identifies it and it is then entered into the PSRS database. Analysis is undertaken by a multidisciplinary team who

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[157] *Ibid.* at § 923(c).
[158] *Ibid.* at § 923(b).
[159] *Ibid.* at § 925(j).
[160] Congressional Budget Office, "Cost Estimate: S.544, Patient Safety and Quality Improvement Act of 2005" (31 March 2005), Congressional Budget Office, online at: <http://www.cbo.gov>. *Ibid.* at § 925(c).
[161] C. Stephen Redhead. "Health Care Quality: Improving Patient Safety by Promoting Medical Errors Reporting" (Congressional Research Service Report) (24 March 2005) at 11.
[162] *Ibid*. at 9. Factors for ASRS's success, according to its administrators, include: it is administered by an independent agency (NASA), rather than the industry's regulator (FAA); timely feedback is given to reporters; and reports are confidential and reporters are granted immunity from disciplinary action for potential violations of federal air regulations provided that they report within 10 days and the violation was inadvertent and was not a criminal offence or an action that indicates a lack of qualification or competency. In addition, the individual must not have been found guilty of a violation in the five year period before the incident occurred.

look for procedural and system deficiencies and their responses are published internally in patient safety bulletins. In its first two years of operation, the external system received a relatively small number of reports (400) as compared to the internal system (140,000 in 5 years), which has been viewed as suggesting that there is a high level of trust in the VA's internal system.[163]

In 1996 the Joint Commission introduced a sentinel events reporting system as part of its accreditation process. Under the accreditation standards relating to sentinel events reporting, accredited organizations are to identify and respond to all sentinel events by undertaking a root cause analysis (RCA) of the event, developing and implementing an action plan for improvement, and monitoring the effectiveness of the changes. While organizations have some flexibility in defining what constitutes a sentinel event, their definition must be consistent with JCAHO's general definition[164] and must, at a minimum, include a list of sentinel events subject to review by JCAHO.[165] Accredited organizations are encouraged to voluntarily report reviewable sentinel events, as it facilitates early consultation with JCAHO during the RCA process, allows events to be analyzed and entered into JCAHO's sentinel event database and permits lessons to be shared with other accredited organizations through its newsletter, *Sentinel Events Alert*. Should JCAHO become aware of a reviewable sentinel event (either from the organization itself or another third party), the organization must prepare and submit to JCAHO an RCA and an action plan within 45 days, or else its risks being placed on accreditation watch. Failure to develop an acceptable RCA and to implement the appropriate changes could result in a loss of accreditation. Organizations concerned about confidentiality can share information with JCAHO using a variety of mechanisms, and JCAHO has advocated for enhanced state and federal legislative protections. Although it accredits nearly 18,000 health care organizations and programs in the US, JCAHO has received relatively few reports on sentinel events. Hospitals have been reported as viewing the program to be "cumbersome, time-consuming, unresponsive and potentially risky."[166] Concerned about the confidentiality of submitted information, hospitals fear the potential for public disclosure and its possible consequences, such as litigation, a loss of its license or accreditation or damage to its reputation.

State Level Adverse Event Reporting Systems

Adverse event reporting systems at the state level can be traced back to the 1970s. Mandatory adverse event reporting programs that preceded the IOM report were

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[163] Commonwealth Fund "Case Study: NASA/VA Patient Safety Reporting System," The Commonwealth Fund, October 2004, online at: <http:www.cmwf.org>.

[164] JCAHO's defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof." "Sentinel Event Policy and Procedures Updated: June 2005", JCAHO webpage, online at:<www.jcaho.org>

[165] Reviewable sentinel events include events resulting in unexpected death or permanent loss of function (not due to the natural course of the patient's underlying condition), rape, suicide, patient abduction, and surgery on the wrong individual or body part. For a full list, see "Part IV: Sentinel Event Policy and Procedures Updated: June 2005", JCAHO webpage, online at:<www.jcaho.org>

[166] *Supra* note 161 at 12.

established in response to medical liability insurance crisis in the 1970s and 1980s (in exchange for legal reforms to medical malpractice laws, states sought greater oversight through reporting systems), highly publicized events involving medical error, and initiatives to improve quality. Historically, these programs were focused on the investigation of individual incidents, rather than the reduction of medical errors. Since the release of the report, several states have either legislatively created new systems or modified existing ones. As of June 2005, twenty-three states had in place statutes or regulations with provisions mandating the reporting of adverse events, including New York, California, Massachusetts, Pennsylvania, Florida, Texas and Minnesota. In its mandatory adverse events reporting system established pursuant to the *Minnesota Adverse Health Care Events Reporting Act of 2003,* Minnesota used a list of 27 serious reportable events in healthcare developed through consensus by the National Quality Forum.[167] The Minnesota Department of Health analyzes the reports by and provides hospitals with feedback. The Department also creates an annual report that is facility specific but uses aggregated data on corrective actions. A one year review of the scheme reported pressure for more disclosure but it was decided that detailed information would remain private.

An example of a state with a voluntary adverse event system is Oregon, and a few states with mandatory reporting systems, such as Florida, have legislation that authorizes the establishment of voluntary reporting systems for close calls or near miss events. Other states lack or are in the process of developing statewide adverse event reporting systems.

The State of New York implemented its first mandatory adverse event reporting system in 1985. Operated by the Department of Health, the current system, the New York Patient Occurrence Reporting and Tracking System (NYPORTS) was established in 1998 with input from stakeholders. Its statutory basis is New York Public Health Law Section 2805-1, Incident Reporting. Under this provision, hospitals are required to report patient deaths and impairments other than those related to "the natural course of the illness, disease or proper treatment in accordance with generally accepted medical standards." Regulations require that the Department of Health be notified of reportable incidents within 24 hours of their occurrence and a certain subset of events must be investigated by

[167] A private, not-for-profit, open membership organization, the National Quality Forum (NQF) is a voluntary consensus standards-setting organization, as defined by the *National Technology Transfer and Advancement Act of 1995, Pub. L. No.* , 104-113, 110 Stat. 775 (NTTAA) and the Office of Management and Budget Circular A-119. The NTTAA was designed to encourage governments to use private sector standards and states that if there are voluntary consensus standards in the private sector, they should be used unless there are good reasons for not doing so. The NQF's consensus process is designed to meet NTTAA requirements. It endorses standards (including quality indicators, reporting guidelines and performance measures) that have achieved consensus from its members. Established as a forum to bring public and private health care stakeholders together to promote standardized quality measures, the NQF is designed to give stakeholders an equal voice and its members include federal and state agencies such as CMS, consumer groups such as Consumers Advancing Patient Safety, hospitals and professional associations such as the American Medical Association and private purchasers, such as General Motors. There are four councils in the NQF: a consumer council, a purchaser council, a research and quality improvement council and a health professional, provider and health plan council. Each member receives one vote within their council and their votes are tallied to determine whether the overall vote of their council is affirmative or negative.

the hospital.[168] Upon completion of the investigation, an investigative report specifying hospital actions taken to analyze and correct identified problems must be provided to the area administrator within 24 hours. All serious occurrences require a root cause analysis. Public Health Law Section 2805-m protects the confidentiality of submitted reports and disclosure is not permitted under New York's Freedom of Information Law.[169] NYPORTS is a secure, internet-based, user friendly system based on a clearly defined list of included and excluded events.[170] The focus is on systems improvement and hospitals can create their own reports to identify trends within their systems or to compare their performance to regional, statewide or peer group aggregate data. Data analysis results and improvement strategies are shared through the *NYPORTS News and Alert* newsletter, publicly available annual reports, letters to CEOs of health facilities and regional forums. Incident reporting is a condition of licensing and the Department of Health has the authority to investigate incidents, impose fines or suspend/ revoke licenses. During 2000, 3 facilities were fined for failure to report or other quality violations.

An article written by the members of the New York Department of Health shares lessons learned over the course of the mandatory adverse events system's development and found a number of elements to be critical to its success.[171] These elements include:

- information is useful and meaningful to those reporting events. Hospitals can retrieve their own data and create their own reports, which provides timelier access than in earlier systems;
- the system is statute based and has legal protections from discovery;
- the system was developed collaboratively with all stakeholders;
- a stakeholder advisory group provides ongoing assessment and recommendations;
- clear and objective reporting criteria exist;
- the system is secure and web-based, and there are adequate resources for its maintenance;
- users receive feedback regarding their own performance;
- data can be analyzed at the facility and state wide level and lessons learned are disseminated.

They note the tension between the public's desire for improved accountability through mandatory systems, while physicians and hospitals fear liability and damage to their reputations and support voluntary systems, whose primary goal is to learn from past

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[168] N.Y.C.R.R. tit. 10, § 405.8.

[169] P Ellen Flink et al., "Lessons Learned from the Evolution of Mandatory Adverse Event Reporting Systems," *Advances in Patient Safety: From Research to Implementation, v.3* (Washington, D.C.: Agency for Healthcare Research and Quality, April 2005) at 137.

[170] *Ibid.* at 138. NYPORTS contains data on 54 specific reportable events.

[171] The article notes how NYPORTS data has been used by facilities and the Department of Health to develop protocols for areas of concern. In the case of wrong-patient/ wrong site events, decreases in these adverse events were noted to be a result of protocol adoption and NYPORTS data analysis. It also highlighted the "potential utility" of mandatory reporting by comparing their reporting numbers with those of JCAHO and its voluntary system. From 1995 to 2003, JCAHO received 106 sentinel event reports from 1326 NY accreditated hospitals, compared to the 11,028 reports of similar occurrences from 250 NY hospitals from 1998 to 2003. *Ibid.*. at 142, 144.

mistakes. They conclude that the NYPORTS system provides accountability within a learning environment.[172]

In 2002, Pennsylvania became the first state to pass legislation that establishes mandatory reporting requirements in relation to both adverse events and near miss incidents. Under the *Medical Care Availability and Reduction of Error (MCare) Act*, health care workers are required to report "serious events"[173] or "incidents"[174] within 24 hours to their medical facility.[175] Facilities are in turn required to report these occurrences to the Patient Safety Authority, an independent state agency. Non-regulatory and non-punitive in nature, the Authority evaluates reports and recommends solutions to facilities for improving health care practices and procedures.[176] Serious events must also be reported to the Department of Health, which is responsible for investigating these events and approving the Authority's recommendations.[177] Under the Act, serious event and incident reports cannot contain the name of the patient or "any other identifiable individual information" and information concerning individual health care workers and patients is not collected.[178] Reports are not discoverable or admissible as evidence in civil or administrative proceedings and cannot be requested under the state's Right-to-Know law.[179] Health care workers are protected from retaliatory action for reporting and the Act permits workers to submit anonymous reports concerning serious events directly to the Authority if they feel the facility has not complied with the Act's requirements.[180] Should the facility learn that a licensed health care worker failed to report a serious event,

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[172] *Ibid*. at 148.

[173] *Medical Care Availability and Reduction of Error Act (MCARE)*, 2002 Penn. Law Act 13,§. 302, 40 Pa. Cons. Stat. § 1303.301 et seq. (2003). A serious event is defined in § 302 as "an event, occurrence or situation involving the clinical care of a patient in a medical facility that results in death or compromises patient safety and results in an unanticipated injury requiring the delivery of additional health care services to the patient. The term does not include an incident." The Patient Safety Authority's 2004 annual report notes that many facilities have reported difficulties determining whether complications are "unanticipated" injuries and the Authority was working towards clarifying this issue (Pennsylvania) Patient Safety Authority, Annual Report for 2004, vol. 1 at 13-14; online: <www.psa.state.pa.us/psa/lib/psa/annual_reports/psa_annual_report_for_2004_-_final_elec_version.pdf>.

[174] An incident is defined at § 302 as "An event, occurrence or situation involving the clinical care of a patient in a medical facility which could have injured the patient but did not either cause an unanticipated injury or require the delivery of additional health care services to the patient. The term does not include a serious event."

[175] The Act defines medical facilities as hospitals, birth centers and ambulatory surgical facilities. Under § 307 of the Act, facilities must have in place a Department of Health approved patient safety plan. The plan must establish a reporting system for health care workers that is accessible 24/7, a patient safety officer to investigate reports and a patient safety committee to evaluate reports and make recommendations.

[176] Patient Safety Authority, *supra* note 173 at 5. Under the Act, the Authority can issue recommendations to a facility or on a statewide level only after consultation and approval by the Department of Health. The Authority is governed by an eleven member board, which by law must include a physician, a nurse, a pharmacist and a non-health care worker. *MCARE* §§ 303(b), 304(a)(7).

[177] *MCARE* § 306. Under this section, approved recommendations may be considered by the Department during licensure decisions, but cannot be mandatory unless adopted as regulations. Statewide recommendations must be made publicly available on the Department's and the Authority's website as per § 304(a)(7).

[178] *MCARE* § 313 (a)-(b); Page 9, Patient Safety Authority, *supra* note 173 at 9.

[179] *MCARE* § 311(a), (d) and (h).

[180] *MCARE* § 308 (c) and 304(b); Patient Safety Authority, *supra* note 173 at 9 & 59.

the facility must notify the appropriate licensing board. The Department of Health may impose penalties against a facility that fails to report a serious event, including an administrative fine of $1,000 a day.

In effect since June 2004, the statewide mandatory requirements apply to over 400 healthcare facilities. [181] Facilities submit reports using the Pennsylvania Patient Safety Reporting System (PA-PSRS), a web-based reporting program that contains a series of 21 questions[182] and a free text narrative section. A clinical team analyzes the reports and the Patient Safety Authority issues *Patient Safety Advisories* via email to health professionals and facilities. The *Advisories* provide information about "actual or potential patient harm" and preventative steps facilities can implement to avoid future incidents.[183] The Authority's 2004 annual report noted that more than 30% of responding hospitals indicated when surveyed that they had made protocol changes based on patient safety information in the *Advisories*.[184] The Authority can look at statewide trends based on aggregate data and under the MCare Act, they must submit an annual report to the general assembly and the public that contains the number of reported serious events and incidents on a geographical or regional level and any recognized patient safety trends identified from the data. The PA-PSRS system also contains analytical tools that managers can use to identify trends within their own facilities. The Authority and its activities are funded through assessments on reporting facilities, the total which cannot exceed 5 million dollars plus CPI adjustments. At the end of 2004, the system had received 70,851 reports, with 95% of reports involving incidents and 5% involving serious events.[185] This compliance level staff attributed to the system's usefulness, the confidentiality protections afforded to the system, and the training provided to facilities.[186]

Other Legislative Instruments

Rules of Evidence and Peer Review Legislation

Nearly every state in the U.S. has some type of statute protecting records from internal hospital review proceedings from discovery or admission into evidence. For example, California, Pennsylvania and Texas have incorporated such protections into law.

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[181] Patient Safety Authority, *supra* note 173 at 1.
[182] The questions gather information about demographics, contributing factors, root causes of serious events and procedures the facility suggest will prevent such an event in the future. *Ibid.*. at 9.
[183] *Ibid.* at 6.
[184] *Ibid.* at 3.
[185] *Ibid.* at 2.
[186] *Ibid.* at 7.

In California, the *California Evidence Code*[187] creates such evidentiary protections. It states:

> 1156. (a) In-hospital medical or medical-dental staff committees of a licensed hospital may engage in research and medical or dental study for the purpose of reducing morbidity or mortality, and may make findings and recommendations relating to such purpose. Except as provided in subdivision (b), the written records of interviews, reports, statements, or memoranda of such in-hospital medical or medical-dental staff committees relating to such medical or dental studies are subject to Title 4 (commencing with Section 2016.010) of Part 4 of the Code of Civil Procedure (relating to discovery proceedings) but, subject to subdivisions (c) and (d), shall not be admitted as evidence in any action or before any administrative body, agency, or person.
>
> (b) The disclosure, with or without the consent of the patient, of information concerning him to such in-hospital medical or medical-dental staff committee does not make unprivileged any information that would otherwise be privileged under Section 994 or 1014; but, notwithstanding Sections 994 and 1014, such information is subject to discovery under subdivision (a) except that the identity of any patient may not be discovered under subdivision (a) unless the patient consents to such disclosure.
>
> (c) This section does not affect the admissibility in evidence of the original medical or dental records of any patient.
>
> (d) This section does not exclude evidence which is relevant evidence in a criminal action.

In Pennsylvania, the Pennsylvania Legislature determined that because the practice of medicine requires a level of expertise which can only be reviewed by other medical professionals, the medical profession should police its own activities through peer review organizations. The Legislature wanted to ensure that patients and the general public are protected and offered quality care by physicians and hospitals by requiring them to maintain appropriate professional standards of care. It also recognized that health care providers hesitate to provide information or to discuss other providers' activities due to concerns that they may face legal proceedings or found liable for their involvement.[188]

Pennsylvania law therefore provides protections to peer review organizations, individuals who serve on peer review committees and information used by these committees.[189] Peer review protection grants immunity to members of peer review organizations and also ensures the confidentiality of certain documents and information used by such organizations in order to foster free and frank communications when discussing matters such as quality assurance, medical cost containment and medical staff credentials and qualifications. Peer review protection is granted listed licensed health care providers: physicians, dentists, podiatrists, chiropractors, optometrists,

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[187] Cal. Evid. Code § 1157.

[188] Office of Legal Affairs, University of Pennsylvania Health System, "Peer Review Protection" online at University of Pennsylvania Health System <http://www.uphs.upenn.edu/legal/prp.html>.

[189] *Peer Review Protection Act*, (63 P. S. § 425.1 et seq.

psychologists, pharmacists, registered or practical nurses and physical therapists. In addition, health care facility administrators, corporations or organizations acting as health care facilities, committees evaluating the quality of health care and credentialing committees are also covered. Individuals who supply information to a peer review committee/organization are generally protected from criminal and civil liability. However, this immunity is not absolute. The individual is not granted immunity if the information he or she reported is unrelated or irrelevant to the peer review committee's functions and scope. The individual is also not protected if the information reported was false and the individual knew or had reason to believe it was false. In addition, the immunity does not apply if the individual's appearance before the peer review organization was motivated by malice.

Documents used and information recorded by peer review committees are not subject to discovery or admissible as evidence in a civil action against a health care provider, if the civil action stems from a matter which is the subject of committee review. However, this protection is not absolute. If the document used by the peer review committee can be obtained from its original source, then the peer review protection does not apply and the document may be disclosed in accordance with applicable law. For example, incident reports concerning a patient fall are not usually protected under peer review. In addition, persons reporting to a peer review committee cannot be compelled to testify at civil hearings as to:

(1) evidence which was produced or relied upon at the proceedings;

(2) conversations, opinions, or evaluations discussed during the proceeding; or

(3) his or her testimony before a peer review protection committee or opinions formed as a result of the committee hearings. However, a person in attendance is not immune from testifying at other civil proceedings as to information within his or her own personal knowledge and learned outside the peer review proceeding.

Texas has similarly enacted such protections, although with broader effect:[190]

> § 161.032. RECORDS AND PROCEEDINGS CONFIDENTIAL.
> (a) The records and proceedings of a medical committee are confidential and are not subject to court subpoena.
> (b) Notwithstanding Section 551.002, Government Code, the following proceedings may be held in a closed meeting following the procedures prescribed by Subchapter E, Chapter 551, Government Code:
> (1) a proceeding of a medical peer review committee, as defined by Section 151.002, Occupations Code, or medical committee; or
> (2) a meeting of the governing body of a public hospital, hospital district, hospital authority, or health maintenance organization of a public hospital, hospital authority, hospital district, or state-owned teaching hospital at which the governing

[190] *Texas Health and Safety Code§ 161.032.*

body receives records, information, or reports provided by a medical committee, medical peer review committee, or compliance officer.

(c) Records, information, or reports of a medical committee, medical peer review committee, or compliance officer and records, information, or reports provided by a medical committee, medical peer review committee, or compliance officer to the governing body of a public hospital, hospital district, or hospital authority are not subject to disclosure under Chapter 552, Government Code.

(d) The records and proceedings may be used by the committee and the committee members only in the exercise of proper committee functions.

(e) The records, information, and reports received or maintained by a compliance officer retain the protection provided by this section only if the records, information, or reports are received, created, or maintained in the exercise of a proper function of the compliance officer as provided by the Office of Inspector General of the United States Department of Health and Human Services.

(f) This section and Subchapter A, Chapter 160, Occupations Code, do not apply to records made or maintained in the regular course of business by a hospital, health maintenance organization, medical organization, university medical center or health science center, hospital district, hospital authority, or extended care facility.

One of the difficulties with these types of protections are that some are written in such a way that they do not protection information disclosed by a person who is in attendance to the quality assurance protections and therefore does not encourage participation by health providers.

Disclosure

A number of states have systems in place which require patient notification after an adverse event. Florida, Nevada, and New Jersey for example, require a system of notifying patient that they are the subject of an adverse incident.[191]

[191] Florida S0002D/H0001D – Title 29, chap. 2003-416, Nev. Rev. Stat. 439.855. N.J. Stat. § 26:2H-12.25.

Patient Safety Law:
From Silos to Systems

Appendix 3: Sector Reports
OCCUPATIONAL HEALTH AND SAFETY

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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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Introduction

Although the federal, provincial and territorial governments in Canada each have authority over workplaces in their jurisdiction, basic similarities in their approach to occupational health and safety regulation exist. All jurisdictions save one have adopted relatively comprehensive occupational health and safety (OHS) statutes that set out a system of overlapping legal duties, rights and responsibilities for workplace stakeholders based on the internal responsibility system.[1] The internal responsibility system is a system of "universal, but *personal*, responsibility" in which every actor is responsible for safety.[2] Under the system, employers and other workplace parties have a general legal duty to take every reasonable precaution to ensure workplace safety and employees have three basic legal rights: the right to refuse to do unsafe work, the right to know or be informed of actual or potential workplace hazards; and the right to participate in health and safety activities through joint health and safety committees or an employee health and safety representative.[3] These rights empower workers to fulfill their legal duty and are expressed through supportive processes and programs. Depending on the number of employees or the type of industry, employers are required by OHS statutes to establish joint health and safety committees of managerial and worker representatives that have the legal right to meet, participate in regulatory inspections and undertake investigations and make recommendations to management.[4] Based on the concept that workplace safety is a shared responsibility and workplace stakeholders are best able to identify, assess and remove or control risks, OHS legislation creates a framework for the internal governance of occupational health and safety. Regulation is necessary, but not sufficient in itself. Leadership is very important for OHS' internal responsibility system to succeed.

OHS law is also based on an external responsibility system, which has been defined as "the authority given to government, by itself, to enforce applicable health and safety legislation."[5] Government responsibilities generally include enforcing OHS legislation and regulations, conducting workplace inspections and promoting education, research and training. Governments have also passed OHS regulations that provide detailed rules and standards for specific areas of risk, such as rules for general blasting, underground mining or fall arrest systems.[6] When these standards or other OHS legislative requirements are not being followed, government health and safety inspectors or officers may issue enforcement orders to address non-compliance, such as an order to stop work or to change a work practice within a certain time frame. Violations can also be addressed

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[1] Norm Keith, *Workplace Health and Safety Crimes: Bill C-45 and the New Westray Criminal Offences* (Markham, Ontario: LexisNexis, 2004) at 98 [Keith, *Workplace Health and Safety Crimes*]. British Columbia lacks a specific OHS statute. OSH regulations made under its *Workers' Compensation Act*, R.S.B.C. 1996, c. 492 contain the elements of the internal responsibility system.

[2] Peter Strahlendorf, "The Internal Responsibility System" (2001) 17:2 OH & S Canada 30 at 31.

[3] Canadian Centre for Occupational Health and Safety, "OH&S Legislation in Canada – Basic Responsibilities", online: <www.ccohs.ca/oshanswers/legisl/responsi.html>.

[4] Keith, *Workplace Health and Safety Crimes*, *supra* note 1 at 102.

[5] Norm Keith, *Canadian Health and Safety Law*, looseleaf (Aurora, Ont.: Canada Law Book Inc, 2005) at 1-24 [*Canadian Health and Safety Law*]; *Occupational Health and Safety Act*, S.N.S. 1996, c. 7, s.1 [Keith, *Occupational Health and Safety Act*].

[6] Keith, *Canadian Health and Safety Law*, *ibid.*

through government prosecution and the laying of charges under OHS statutes. Punishable through fines or imprisonment, OHS regulatory offenses are quasi-criminal, strict liability offences. In addition, the *Criminal Code* was amended in 2004 to create a new health and safety duty that requires everyone who directs how an individual performs a task to take reasonable steps to prevent bodily harm to that person or others. [7] A breach of this duty could result in a charge of OHS criminal negligence or other criminal offences. Relying on both internal and external regulatory measures, Canadian OHS law sets up a system of regulated self-regulation, where on the whole governments tend to promote "private resolution of safety and health concerns through technical advice and support to employers and workers and, when private resolution fails, through inspections and prosecutions."[8]

In addition, each jurisdiction provides employees with compensation for workplace injuries through no fault worker compensation systems. In situations where the system applies, benefits are available from an accident fund which is funded by employer premiums and in exchange, employers are protected from tort liability Workers' Compensation Boards (WCB) or Commissions administer the statutory schemes. Most jurisdictions treat occupational health and safety and workers' compensation as separate legislative areas.[9] However, in British Columbia, they have been merged into one legislative scheme with the aim of harmonizing their goals, while in other jurisdictions, such as New Brunswick, one body administers both the OHS and workers' compensation legislation. In Nova Scotia and in some other provinces, workplace insurance and health and safety prevention and education rests with the WCB, while the OHS Division of the Department of Environment and Labour is responsible for administering and enforcing the provincial OSH legislation.[10]

In general, it is important to note that there is limited and mixed evidence on the effect of introducing OHS Regulation on illness and injury outcomes. A study of OHS regulation in New York and Texas concluded that its introduction in New York increased the frequency of some injury types whereas its introduction in Texas reduced the frequency of some types of injury but increased it for others.[11] Lastly, a study of the introduction of OHS in Quebec concluded that the introduction of OHS regulation reduced frequency in some industries.[12]

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[7] Keith, *Canadian Health and Safety Law*, *ibid.* at 10-78-10-80.
[8] Randy S. Rabinowitz & Mark M. Hager, "Designing Health and Safety: Workplace Hazard Regulation in The United States and Canada" (2000) 33 Cornell Int'l L.J. 373 at 396-97 [Rabinowitz].
[9] Keith, *Canadian Health and Safety Law*, *supra* note 5 at 1-7.
[10] Workers' Compensation Board of Nova Scotia, "Prevention Services," online: <http://www.wcb.ns.ca/new/prevention.php.>.
[11] W. Currington, "Federal versus State Regulation: The Early Years of OSHA" (1988) 69 Soc Sci Q 341.
[12] P. Lanoie, "The Impact of Occupational Safety and Health Regulation on the Risk of Workplace Accidents in Quebec, 1983-87" 27 J Human Resources 643; P Lanoie, "Safety Regulation and the Risk of Workplace Accidents in Quebec" (1992) 58 Southern Economic J 950.

Jurisdiction

Approximately 10% of workplaces in Canada fall within federal jurisdiction, while 90% fall within provincial jurisdiction.[13] The Canadian *Constitution Act, 1867* does not explicitly refer to OHS in its division of powers between federal and provincial governments. Consequently, the courts have determined where jurisdictional authority lies.[14] Occupational health and safety falls primarily under provincial jurisdiction as part of the broader provincial responsibility for labour relations. However, the federal government administers labour laws (including OHS laws) in the following sectors that have been either explicitly designated to be under federal jurisdiction in the *Constitution Act 1867* or have been ruled to be federal by the courts: industries that are extra-provincial or international (e.g., various transportation sectors); telecommunications; banking; and federal crown corporations and agencies.[15] The *Canadian Charter of Rights and Freedoms* applies to OHS law. A list of acts which address occupational health and safety at the provincial and federal level are included as an appendix at the end of this report.[16]

Specific Elements of Canadian OHS Law:

The Internal Responsibility System

Widely regarded as the conceptual foundation of OHS law in Canada, the internal responsibility system holds that workplace stakeholders have the primary and shared responsibility to ensure workplace safety, as they are best positioned to effectively identify, assess and control or eliminate risk.[17] Key elements of the system include legislating positive duties and responsibilities for various stakeholders and providing certain rights to workers, so that the principal parties involved in managing and improving occupational health and safety are workplace stakeholders.[18] Although it is not an exhaustive definition, Nova Scotia was the first Canadian jurisdiction to explicitly define the internal responsibility system in its legislation:

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[13] Keith, *Workplace Health and Safety Crimes*, *supra* note 1 at 97.
[14] *Ibid.*
[15] Government of Canada, "Jurisdiction of the Federal Government, the Provinces and the Territories in the Field of Occupational Health and Safety," online: HRSDC <http://www.hrsdc.gc.ca/asp/gateway.asp?hr=/en/lp/spila/clli/ohslc/02jurisdiction_federal_government_and_provinces.shtml&hs=oxs>; Part II of the *Canada Labour Code*, R.S.C. 1985, c. L-2 dealing with OHS does not apply to specific undertakings that are regulated by the *Nuclear Safety and Control Act*, R.S.C. 1997, c. 9.
[16] See Canadian Centre for Occupational Health and Safety, online: CCOHS < http://www.ccohs.ca/legislation/fulllist.html> for a complete list of provincial and federal enviroOSH legislation.
[17] Keith, *Canadian Health and Safety Law*, *supra* note 5 at 2-2.
[18] Depending on the jurisdiction, stakeholders can have legal duties include contractors, employers, supervisors, workers, licensees, professional engineers, architects, directors, officers and suppliers. See *Canadian Health and Safety Law*, *ibid*.

2. The foundation of this Act is the Internal Responsibility System which
   (a) is based on the principle that
      (i) employers, contractors, constructors, employees and self-employed persons at a workplace, and
      (ii) the owner of a workplace, a supplier of goods or provider of an occupational health or safety service to a workplace or an architect or professional engineer, all of whom can affect the health and safety of persons at the workplace,
   share the responsibility for the health and safety of persons at the workplace;
   (b) assumes that the primary responsibility for creating and maintaining a safe and healthy workplace should be that of each of these parties, to the extent of each party's authority and ability to do so;
   (c) includes a framework for participation, transfer of information and refusal of unsafe work, all of which are necessary for the parties to carry out their responsibilities pursuant to this Act and the regulations; and
   (d) is supplemented by the role of the Occupational Health and Safety Division of the Department of Labour, which is not to assume responsibility for creating and maintaining safe and healthy workplaces, but to establish and clarify the responsibilities of the parties under the law, to support them in carrying out their responsibilities and to intervene appropriately when those responsibilities are not carried out. [19]

As indicated in Part 2(c) of Nova Scotian definition, a critical part of the IRS system is the granting of three basic workers' rights to empower them in relation to OHS:

i) the right to know about workplace dangers, such as how to identify and protect themselves from risks. The Workplace Hazardous Materials Information System (WHMIS), a national, legislative regime of hazardous materials labeling, handling measures and training, is a manifestation of the broader right to know; [20]
ii) the right to participate in OHS decisions without reprisal, usually through OHS committee or individual representatives; and
iii) the right to refuse dangerous work without reprisals.[21]

The right to participate is represented in the legislative requirement for the establishment of Joint Health and Safety Committees, which are forums that involve both employers and employees in identifying, monitoring and improving occupational health and safety.[22] While everyone in the system has a personal and shared responsibility for ensuring a safe workplace for themselves and others, the system recognizes that one's

[19] *Occupational Health and Safety Act, supra* note 5 at s. 2.
[20] All Canadian jurisdictions have amended their legislation to address the WHMIS program and passed regulations for its implementation. See Keith, *Canadian Health and Safety Law, supra* note 5 at 4-1-4-2.
[21] Government of Saskatchewan Department of Labour, "Occupational Health and Safety Committee Manual: The Internal Responsibility System for Occupational Health and Safety," online: Saskatchewan Labour <http://www.labour.gov.sk.ca/safety/committee-manual/chapter-1/internal.htm >.
[22] All Canadian jurisdictions have statutory provisions for joint committees, however, whether employers are legally required to establish them in a given jurisdiction may depend on either the number of employees or the type of industry.

ability to do so is tied to the level of authority and control one possesses. Given their greater degree of control over the workplace, employers "ultimately and practically" have the highest degree of legal responsibility under the IRS system.[23] Although the structure of an internal responsibility system varies from province to province, the IRS system overall "provides legal requirements, standards and procedures for workplace health and safety, promotes self-regulation of workplace hazards, and reduces the need for government regulators to intervene in the workplace."[24]

Legal responsibilities and duties

As part of the IRS system of shared responsibility, Canadian OHS law creates an accountability framework for occupational health and safety by defining the legal responsibilities and duties of various stakeholders, such as employers, contractors, suppliers, owners, supervisors and employees. There is some variation across jurisdictions as to which workplace stakeholders have legislatively defined duties and these duties may overlap. Duties are more than normative statements and their breach is punishable by a variety of statutory enforcement mechanisms. No one stakeholder is exclusively responsible for ensuring compliance with OHS laws. The responsibilities of governments, as well as the common legal duties assigned to employers and employees as part of the internal responsibility system, will be addressed below.

Government

OHS legislation establishes the duties and responsibilities of government actors. Generally, provincial and territorial Ministers and Deputy Ministers of Labour have been given the broad responsibility of administering and enforcing OHS legislation. Other responsibilities may include the resolution of OHS conflicts, the promotion of education, training or research and the setting or approval of standards or codes of practice. Under Nova Scotia's OHS legislation, the Minister is responsible for the supervision and management of the Act. [25] The legislation explicitly states that the OHS division of the Department of Labour is not responsible for creating and maintaining safe workplaces, but rather its role is to support the internal responsibility system through advice and intervention when appropriate. [26] The Division is also charged with maintaining reasonable standards, promoting and/or conducting OHS research and education programs and preparing, either alone or with the WCB, OHS statistics.[27]

Employers

[23] Keith, *Workplace Health and Safety Crimes*, *supra* note 1 at 104.
[24] *Ibid.*
[25] *Occupational Health and Safety Act*, *supra* note 5 at s. 6.
[26] *Ibid.* at s. 2.
[27] *Ibid.* at s.9. Although it would appear to fall under the OHS Division's responsibility for conducting educational programs, health & safety prevention education is being undertaken by the provincial WCB.

Canadian OHS laws contain a number of common duty provisions for employers. All jurisdictions have in place a general duty for employers to take all reasonable precautions to ensure a safe and healthy workplace for workers.[28] This overarching general duty clause can require employers to meet a higher standard than may be specified in the regulations, if the circumstances warrant such an action.[29] Other common legal duties for employers include a duty to:

- establish a OHS policy or program, either in general or in relation to specific hazards;
- ensure workers are properly trained and supervised;
- warn workers about potential workplace hazards and provide them with information and training around how to safely handle hazardous substances under the WHMIS program;
- establish and cooperate with a joint health and safety committee or OHS representatives;
- inform workers of their legal rights and responsibilities or post the relevant OHS legislation or regulations;
- report to the applicable agency serious illnesses, injuries, or accidents, which is accompanied by a duty to investigate and take corrective measures.[30]

Employees

Just as employers have a general duty to ensure the safety of employees, so too employees have a legal duty to take reasonable care in the workplace to protect both themselves and others. Workers are also generally required by law to co-operate with their employer, co-workers, joint health and safety committees or representatives, and government actors in relation to OHS. In most jurisdictions, there is an express duty on workers to use the personal protective equipment required by the employer or under OHS law. Some jurisdictions also give workers a positive legal duty to inform the employer (or his or her agents) of any dangerous condition that is or may affect the safety of the workplace.

Joint Health and Safety Committees

A key aspect of the internal responsibility system, joint health and safety committees act as a forum for encouraging cooperation between workplace stakeholders on occupational health and safety issues and a means of enabling workers' participation rights. Canadian OHS law prescribes the circumstances in which an employer is obligated to establish a Joint Health and Safety Committee. Their establishment may be dependant on ministerial discretion, the nature of the industry, or a legislated threshold of

[28] British Columbia, *A Comparison of Fundamental Rights and Duties in Canadian Occupational Health and Safety Statutes* (Issues Paper #6, submitted to the Royal Commission on Workers Compensation in British Columbia) by George Bryce & George Heinmiller at 7.
[29] *Ibid.*
[30] *Ibid.* at 8.

employees. Many jurisdictions require committees in workplaces with twenty or more employees.

Committees act to ensure workplace safety in a relatively autonomous manner, although they must comply with the broad policy objectives of OHS legislation. Committees may receive, investigate and resolve complaints, and make recommendations to employers about OHS. They may also assist in resolving work refusals and stoppages and participate in government inspections. Certain jurisdictions require committees to undertake their own regular inspections.[31] Further, "in many jurisdictions, health and safety committees must be consulted before new OHS programs are introduced" by employers.[32] Committees also monitor compliance with workplace health and safety requirements. However, when voluntary compliance is not forthcoming, the government maintains a formal enforcement role.[33] Be it explicit or implicit, most jurisdictions generally grant committees access to relevant OHS information, such as accident data and investigation reports.[34] Committee functions listed in Section 31 (1) of Nova Scotia's OHS Act include:

(a) the co-operative identification of hazards to health and safety and effective systems to respond to the hazards;
(b) the co-operative auditing of compliance with health and safety requirements in the workplace;
(c) receipt, investigation and prompt disposition of matters and complaints with respect to workplace health and safety;
(d) participation in inspections, inquiries and investigations concerning the occupational health and safety of the employees and, in particular, participation in an inspection referred to in Section 50 [government inspections];
(e) advising on individual protective devices, equipment and clothing that, complying with this Act and the regulations, are best adapted to the needs of the employees;
(f) advising the employer regarding a policy or program required pursuant to this Act or the regulations and making recommendations to the employer, the employees and any person for the improvement of the health and safety of persons at the workplace;
(g) maintaining records and minutes of committee meetings in a form and manner approved by the Director and providing an officer with a copy of these records or minutes on request.

One analyst sums up the authority of a committee by stating that "although joint committees investigate and advise employers with limited decision making powers, they may promote health and safety in several *key* ways: by inducing employee-management cooperation, by giving employees a voice and forum for registering their knowledge and

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[31] British Columbia, *The Role of Joint Committees in Workplace Health and Safety: A Review of the Legislation and Previous Studies* (submitted to the Royal Commission on Workers Compensation in British Columbia) by John O'Grady (May 1998) at 15 [*Role of Joint Committees in Workplace Health and Safety*].
[32] Keith, *Workplace Health and Safety Crimes*, *supra* note 1 at 102.
[33] Rabinowitz, *supra* note 8 at 401.
[34] Keith, *Role of Joint Committees in Workplace Health and Safety*, *supra* note 31 at 15.

concerns, and by promoting union attention to and possible collective bargaining on health and safety issues."[35] However, critics of Canadian OHS law relating to joint committees note they are primarily advisory and lack real power to institute changes. In Ontario, certified committee members, who have specialized training, have the statutory authority to commence bilateral or unilateral work stoppages.[36] Ontario also has a legal mechanism through which committees can hold employers accountable for their recommendations. As a matter of law, employers must respond in writing to committee recommendations within 21 days and provide a timetable for implementing those recommendations they agree to and reasons for why they will not implement others.[37] If sound reasons are not given for refusing to implement a recommendation, a committee member may take their complaint to government enforcement officials.

Canadian OHS law also sets out requirements regarding committee composition and procedures. Most jurisdictions prescribe the minimum number of meetings that committees must have and require the keeping of minutes. At least half of the committee members are generally required by law to be non-managerial employees chosen by their fellow employees or their union. Workers and management are said to have equal interests in OHS joint committees. However, some regard this as an idealistic notion that ignores Canada's history of adversarial labor-management relations.[38] Most jurisdictions prohibit employers and employees from discriminating against employees who serve on joint committees and execute health and safety duties.[39] Designed to ensure that worker safety concerns are voiced, many jurisdictions require the appointment of a health and safety representative in workplaces where there are too few employees to form a committee.[40]

Joint committees of employees and management appear to have many benefits: increasing manager-worker trust, attempting to eliminate adversarial environments, serving as a useful investment to employers as evidence of due diligence if faced with

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[35] Rabinowitz, *supra* note 8 at 411.
[36] Keith, *Canadian Health and Safety Law*, *supra* note 5 at 2-25.
[37] *Occupational Health and Safety Act*, R.S.O. 1990, c. 0.1, ss. 9(20), 9(21).
[38] Richard Fidler, "The *Occupational Health and Safety Act* and the Internal Responsibility System" (1986) 24 Osgoode Hall L.J. 315 at 315-52 [Fidler].
[39] Keith, "Designing Health and Safety," *supra* note 33 at 411.
[40] Ottawa, Human Resources and Skills Development Canada, *Canadian Legislation Relating to Safety and Health Representatives* (Ottawa: Labour Law Analysis, International and Intergovernmental Labour Affairs, Labour Branch, 2005) at 5. According to several studies, unionized workplaces are more likely to be organized and safer workplaces in the Canadian and international context. Union supported health and safety committees according to some studies, have "a significant impact on reducing injury rates." (Canadian Ministries of Labour 1993) Further, "78-79% of unionized workplaces reported high compliance with health and safety legislation with only 54-61% of non-unionized workplaces reporting such compliance." (Ontario Workplace Health and Safety Agency studies 1994 and 1996) In 1995, the World Bank stated that "trade unions can play an important role in enforcing health and safety standards. Individual workers may find it too costly to obtain information on health and safety risks on their own, and they usually want to avoid antagonizing their employers by insisting that standards be respected." This information was quoted by the UNISON Scotland, online: <http://www.unisonscotlandlaw.co.uk/article_view.html?id=520>. Studies also indicate that Unions and joint committees are both effective in curtailing safety risks because consultation methods used to target safety risks improve the safety culture in a workplace.

charges, and reducing workplace injuries.[41] Some studies indicate that joint committees create more positive and trusting relationships between labour and management representatives, and argue that employers and employees both recognise benefits in the decision to create joint health and safety committees. According to one analysis, employment lawyers have directly attributed positive OHS practices in the workplace to these committees. In turn, this gained trust "leads to a less legalistic approach to resolving health and safety issues" in the workplace.[42] As such, some suggest that employers recognize the value of joint committees in creating safe and cost-effective work environments due to decreased accident rates and lower workers' compensation levies.[43] Similarly, the Ontario Workplace Health and Safety Agency determined that manufacturers attribute lowered accident rates and compensation costs to their use of health and safety committees.[44] A review of studies concerning joint OHS committees done for the BC government in 1998 identified three main factors that influence the effectiveness of committees: their rights to information, their level of training and the level of managerial commitment. [45]

One reason that joint committees are regarded as beneficial may be the ability of such committees to create accessible channels of communication and thereby foster greater transparency. Studies tend to agree that open pathways of communication are crucial in order to avoid accidents and workplace injuries. But not all studies indicate that joint committees are the most effective means by which safety issues are dealt with. Writing about Australian OHS, one analyst argues that when committees are asked to solve specific problems, they are often less effective than individual decision-makers. However, the same study concludes that committees do have good "judgment" regarding safety issues and produce effective safety solutions when members meet for consultations, but only after they have brainstormed specific dilemmas or issues independent of each other prior to meeting as a group.[46]

Standards and Guidelines

OHS legislation stipulates who has the authority to make regulations and orders setting standards or codes of practice. In most provinces, authority to set or approve standards lies with the Minister under the authority of the Governor in Council or the Lieutenant Governor in Council. In other provinces, legislation grants Worker Compensation Boards the power to set workplace standards. OSH regulations generally contain standards that are either sector specific (i.e., standards for the mining industry or health care facilities) or subject specific (i.e., hazardous materials). OHS regulations may incorporate by reference industry or technical standards, such as those passed by the

[41] John Beaufoy, "Legal Update: Occupational Health and Safety," *Canadian Lawyer* 18:5 (June 1994) 42 at 42 [Beaufoy].
[42] *Ibid*.
[43] *Ibid*.
[44] *Ibid*.
[45] *Role of Joint Committees in Workplace Health and Safety*, *supra* note 31 at 15.
[46] John Culvenor, "Comparison of Team and Individual Judgments of Solutions to Safety Problems" (2003) 41 Safety Science 543 at 551.

Canadian Standards Association, which makes them legally enforceable. When standards and rules do not adequately protect employees from safety risks, the "general duty may require prevention beyond what specific standards require."[47]

Workplace Conditions

Quebec's OHS statute is unique in Canada in that it expressly gives every worker the right "to working conditions that have proper regard for his health, safety and physical well-being."[48] B.C. was the first jurisdiction to legislate duties around workplace ergonomics and its OHS regulations require employers to identify and minimize or eliminate where possible risks around musculoskeletal injury (MSI).[49] In the area of workplace violence and harassment, certain jurisdictions, such as Alberta, Saskatchewan, and British Columbia, have legislative initiatives that address one or both of these issues. In Alberta, employers are required to develop policies around workplace violence, train employees on how to identify and respond to workplace violence and undertake an assessment of the potential for violence in their workplace.[50] In Saskatchewan, OHS legislation places a duty on employers, to the extent that it is reasonably possible, to ensure workers are not exposed to harassment in the workplace, while in other provinces and territories, harassment is dealt with through human rights legislation.[51] Some studies suggest that harassment falls within OHS legislation as a legitimate reason for an employer to use his or her right to refuse work.[52]

Complaint Mechanisms

OHS law outlines the basic right of an employee to lodge a complaint or report OHS concerns without fear of discrimination by employers, unions or others.[53] OHS legislation in each province defines several key relationships designed to ensure that employees have a way to communicate OHS concerns for purposes of accountability. At the most basic level, employees may take concerns to their immediate supervisors or employers. They may also raise concerns with OHS committees and representatives. To facilitate this right, an employer is responsible for posting the names and locations of committee members. Under Section 17 (2) of Nova Scotia's *Occupational Health and Safety Act*, employees have a positive duty to report dangers and are given of hierarchy of actors to report to (first, supervisors, followed by the OHS committee or representative and lastly, the government's OHS Division) in case the response at one level is not satisfactory.

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[47] Rabinowitz, *supra* note 8 at 402.
[48] *An Act Respecting Occupational Health and* Safety, R.S.Q. c. S-2.1, s. 9.
[49] Paul Jay, "Occupational Health and Safety" *Canadian Lawyer* 22:7 (July 1998) 37 at 37 [Jay].
[50] *Alberta Occupational Health and Safety Code 2003* at ss. 389, 391.
[51] Beaufoy, *supra* note 41.
[52] *Ibid.* at 43.
[53] However, there is a discrepancy between provinces in the language used to discuss when an employee can complain/report. Some OHS legislation states that it is a "right" while other legislation states that an employee "*may* refuse to do acts."

Under Canadian OHS law, employees also have the important legal right to refuse to do unsafe work. In British Columbia and Alberta, this right is expressed as a legal duty on workers not to perform dangerous work. In a case where an employee refuses work on reasonable grounds, he or she cannot be discharged, disciplined or discriminated against. Generally, this right allows an employee to refuse work where there is a perceived unusual risk or danger, even where there is no imminent risk. However, in Alberta, workers have the above duty only when there are reasonable and probable grounds to believe that the work represents an imminent danger. Some jurisdictions have also placed restrictions on the exercise of this right or made it an offence to abuse it. For example, under Quebec's OHS Act, the right of refusal may not be used if the danger is an inherent part of a worker's job and the right is suspended when exercising it would put the life, health, safety or physical well-being of others in immediate danger. In practice, workers who belong to a union exercise this right more often than non-unionized workers, which reflects the power imbalance in non-unionized workplaces and suggests in part a discrepancy regarding awareness.[54]

While there are variations between jurisdictions, generally, the process required by OHS law following a work refusal starts with an investigation of the situation by the employer or supervisor. If the employee finds the outcome unsatisfactory, then the employee may take his or her concerns to the OHS committee or representative. The last option available to resolve issues of concern is to approach the government agency responsible for occupational health and safety. Section 43 of Nova Scotia's Occupational Health and Safety Act outlines the procedures to be followed after a work refusal:

> 43 (1) Any employee may refuse to do any act at the employee's place of employment where the employee has reasonable grounds for believing that the act is likely to endanger the employee's health or safety or the health or safety of any other person until
>
> (a) the employer has taken remedial action to the satisfaction of the employee;
>
> (b) the committee, if any, has investigated the matter and unanimously advised the employee to return to work; or
>
> (c) an officer has investigated the matter and has advised the employee to return to work.
>
> (2) Where an employee exercises the employee's right to refuse to work pursuant to subsection (1), the employee shall
>
> (a) immediately report it to a supervisor;
>
> (b) where the matter is not remedied to the employee's satisfaction, report it to the committee or the representative, if any; and
>
> (c) where the matter is not remedied to the employee's satisfaction after the employee has reported pursuant to clauses (a) and (b), report it to the Division.
>
> (3) At the option of the employee, the employee who refuses to do any act pursuant to subsection (1) may accompany an officer or the committee or representative, if any, on a physical inspection of the workplace, or part

[54] Rabinowitz, *supra* note 8 at 413.

> thereof, being carried out for the purpose of ensuring others understand the reasons for the refusal.

Investigation and Enforcement

As part of the external responsibility system, government appointed inspectors act as occupational health and safety enforcement officers and their general role under OHS law is summarized below:

> Inspectors consult, monitor compliance, and investigate fatalities, work refusals, and hazard complaints. Decisions whether to inspect are discretionary, except for mandatory work refusal investigations. ... [Government] targets inspections using employer-specific injury and illness information. Inspectors enter workplaces without warrants or prior notice. They may take samples, seize documents or things, and consult with outside experts and employees. Employee joint committee members and representatives may accompany inspectors and must be compensated for time spent with inspectors.[55]

Should inspectors determine that OHS law has been contravened, they have the statutory authority to issue orders or directions that may stipulate corrective measures to be taken, employee-removal, equipment or workplace shut-down and other penalties and fines. Canadian jurisdictions have granted rights of appeal to workplace stakeholders in relation to these orders.

According to a 1986 analysis of OHS law in Ontario, relying on inspectors for many types of enforcement does not promote an environment in the workplace where workers' feel included in the process of OHS regulation. Recommendations on how to improve the IRS in order to make it more effective included a call to give "worker health and safety committee members and representatives the right to unilaterally shut down unsafe operations, to be present during all testing or monitoring and to do their own testing and monitoring with their own experts."[56] However, one study does warn that "there are obvious limits to what these measures can accomplish in a society in which private owners control investment decisions and production process. As long as employers have the power to discipline and lock out workers and as long as workers remain largely unorganized, a heavy burden falls on the government agency responsible for administering the protective legislation."[57] Another way to promote safety and ensure that employees are treated equitably is to stress the importance of government inspector and joint committee member cooperation. Inspectors should be prepared to backup committee decisions and listen to recommendations when they are trying to curtail employer-resistance to regulatory standards.[58]

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[55] *Ibid.* at 403.
[56] Fidler, *supra* note 38 at 349.
[57] *Ibid.* at 350.
[58] *Ibid.* at 352.

A number of studies, Canadian and otherwise assess the impact of OHS inspections on illness and injury outcomes. The results are somewhat mixed. Some suggest that inspections reduce the frequency and/or severity of injuries, some suggest that inspections reduce frequency when first employed but do not after a period of time has passed, some that the type of inspections makes a difference with complaint inspections reducing frequency, others that inspections increase frequency or have no effect on it.[59] It is difficult therefore to assess the utility of inspections as a means of reducing workplace injury.

According to one employment lawyer, "smaller fines do have a positive effect" when they are directed at persons in supervisory roles, "since they force line managers to take responsibility for health and safety problems, instead of leaving the obligation to 'the company.'"[60] Targeting supervisors is also an economically appealing option for both governments and companies who note that large-sum fining may result in decreased investor confidence. Overall, though, some analysts suggest that it is difficult to prove if large fines directed at companies have a deterrent effect.[61] Analysts are also divided on whether citations and fines impact upon illness and injury outcomes. Some suggest that inspections with penalties reduce injury frequency, others that injury frequency is initially reduced but remains static or increases later, others that it actually increases injury frequency.[62]

Occupational health and safety inspectors may also recommend the prosecution of violations as an additional though rarely used means of deterrence. Quasi-criminal in

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[59] JT Chung, *The Effectiveness of Enforcement Activities of the Occupational Safety Program of Korwa* (PhD Thesis, American University, 1990) [unpublished]; Wayne B. Gray & John Mendeloff, "The Declining Effects of OHSA Inspections on Manufacturing Injuries, 1979-1998" (2002) NBER Working Paper 9119 (Washington: National Bureau of Economic Research) [Gray & Mendeloff]; Wayne B. Gray & Scholz, "Analysing the Equity and Efficiency of OSHA Enforcement" (1991) 13 Law & Pol'y 185 [Gray & Scholz, "Analysing"]; Ruser & Smith, "Reestimating OSHA's Effects: Have the Data Changed?" (1990) 26 J Human Resources 212; Scholz & Gray, "OSHA Enforcement and Workplace Injuries: A Behavourial Approach to Risk Management" (1990) 3 J Risk & Uncertainty 283 [Scholz & Gray, "OSHA Enforcement"]; Scholz & Gray, "Can Government Facilitate Cooperation? An Informational Model of OSHA" (1997) 41 Am J Political Science 693 [Scholz & Gray, "Can Government Facilitate Cooperation?"]; Sha, *Accident Rates, Workers' Compensation and Safety Regulations* (PhD Thesis, State University of NY at Stony Brook, 1995) [unpublished] [Sha]; Smith, "Impact of PSHA Inspections on Manufacturing Injury Rates" (1979) 14 J Human Resources 145; Baggs *et al.*, *Observed Associations Between WISHA Activities and Compensable Claims Rates* (Olympia WA: Safety and Health Assessment and Research for Prevention (SHARP) Program, 2001); Guo, *The Influence of OSHA Inspectors' Detection Capabilities on OSHA's Effectiveness: Evidence From Panel Data, 1979-1985* (PhD Thesis, Clark University, 1999) [unpublished] [Guo]; Kim 1991The Political Economy of OSHA Regulation: A Poled Tiem Analysis (PhD Thesis, University of Georgia, 1991) [unpublished] [Kim]; Lanoie, *supra* note 12, Lanoie & Streliski, "L'impact de la reglementation en matiere de sante et securitie du travail sur le risqué d'accident au Québec: de nouveaux resultats" (1996) 51 Relations Industrielles 778 [Lanoie & Streliski]; DP McCaffrey, "An Assessment of OSHA's Recent Efforts On Injury Rates" (1983) 18 J Human Resources 131; W. Kip Viscusi, "The Impact of Occupational Safety and Health Regulation, 1973-1983" (1986) 17 Rand J of Economics 567 [Viscusi].

[60] Jay, *supra* note 49 at 39.

[61] See *e.g.* John Hill in Jay, *supra* note 49.

[62] Gray & Mendeloff, *supra* note 59; Gray & Scholz, "Analysing", *supra* note 59; Guo, *supra* note 59; Kim, *supra* note 59; Lanoie *supra* note 12; Lanoie & Streliski, *supra* note 59, Viscusi, *supra* note 59.

nature, most OHS regulatory offences are strict liability offences. For strict liability offences, the prosecution need only prove beyond a reasonable doubt the act was committed, unlike criminal offences where a mental element, or intent, must also be proven. Defendants may raise the defense of due diligence and one branch of the defense allows workplace stakeholders to argue they have taken reasonable steps to comply with OHS law. Offences are punishable through fines or imprisonment. In Nova Scotia, offences carry a maximum sentence of two years imprisonment or a fine of $250,000, plus up to $25,000 per day for each additional day the offence continues.

The criminal sanctions model of enforcing OHS law has been growing in last decade and in November 2003, the federal government used, in area of occupational health and safety, its authority to criminalize conduct. Bill C-45 amendments to the *Criminal Code* established new rules by which organizations can be held criminally liable and created an OHS legal duty within the *Criminal Code* for the first time in Canadian legal history. In force since March 2004, these amendments were motivated by the 1992 Westray mine disaster in Plymouth, Nova Scotia that resulted in the deaths of 26 workers.[63] Contained in the criminal negligence provisions of the *Criminal Code*, the new duty states that "everyone who undertakes, or has the authority, to direct how another person does work or performs a task is under the legal duty to take responsible steps to prevent bodily harm to that person, or any other person, arising from that work or task."[64] By introducing a legal duty to ensure workplace safety within the *Criminal Code*, the federal government has arguably created one overarching standard that covers OHS throughout the country.[65]

OHS Law and WCB Injury Compensation

Tort liability in OHS has been largely replaced by a social insurance system established by workers' compensation legislation. The WCB mandatory no-fault insurance scheme is the primary way that jurisdictions resolve OHS liability. Each Canadian province has enacted workers' compensation laws and where applicable, coverage is compulsory. Injured employees receive compensation for injuries and illnesses that arise in the workplace or are related to their employment in the form of medical care and wage replacement benefits. Dependents receive survivor's benefits in the case of fatalities. However, workers' compensation is exclusive and employees and their dependents lose the right to sue under the system. Workers' compensation does not usually grant damages for non-economic losses, such as pain and suffering. The exception is Ontario, where standardized non-economic compensation is awarded for permanently impaired workers.

The system is funded through employer premiums. Employer premiums are assessed based on injury levels associated with their industry and may vary up or down depending on the individual employer's safety record. This type of variation "creates a link between

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[63] At Westray, mine managers failed to follow proper safe mining procedures, workers continued to work despite their OHS concerns because of unemployment fears, and government regulators did not rigorously enforce OHS requirements. See Keith, *Workplace Health and Safety Crimes*, *supra* note 1 at 15-18.
[64] R.S.C. 1985, c. C-46, s. 217.1.
[65] Keith, *Workplace Health and Safety Crimes*, *supra* note 1 at 99.

workers' compensation cost and safety and health performance. At least one province tightens that link by specifying compliance with health and safety regulations as an explicit criterion for individualized assessments."[66] In addition to their OHS reporting duties, employers are also required under workers' compensation legislation to report workplace injuries and accidents to WCBs, although these reports differ in that they require medical details and do not normally lead to potential prosecutions, as OHS reports may.

The WCB no-fault system aims to both compensate for workplace injuries or illnesses and to deter injuries and illnesses by preventing incidents and accidents from occurring in the workplace. Advocates of no-fault liability systems "emphasize improved deterrence, or injury prevention, and prompt mitigation of injuries that do occur."[67] Further, "deterrence is meant to be increased through more systematic case finding, more expert resolution of claims, enhanced monitoring and education, and better economic incentives."[68] WCB programs are generally thought to be more efficient than the tort system at providing compensation. However, studies have also suggested that a no-fault system can create moral hazards:

(1) "When premiums have not been fully experience-rated, employers have been less prone to provide a safe work environment;
(2) Even when employers do promote safety, employees may become more careless when compensated for injuries;
(3) When well insured, injured workers have a tendency to take longer to return to work."[69]

Additional Federal Legislative Initiatives relating to OHS

The Canadian Centre for Occupational Health and Safety (CCOHS)

Established in 1978, the Canadian Centre for Occupational Health and Safety (CCOHS) is a federal government agency listed under Schedule II of the *Financial Administration Act* as an "independent departmental corporation," and is accountable to Parliament through the federal Minister of Labour. While created by statute, the agency is not legally involved in OHS accountability or enforcement, but rather is mandated to improve performance through advice, information and education. At the national level, the CCOHS serves as an OHS information repository, with an extensive advisory role for governing bodies (provincial, national and international) and for employers and employees. The CCOHS aims to find "the most effective methods of assembling, analyzing, and disseminating information and advice" to fulfill its mandate to prevent occupational diseases, injuries and fatalities and increase employer and employee

[66] Rabinowitz, *supra* note 8 at 419.
[67] See Randall R. Bovbjerg & Frank A. Sloan, "No-Fault for Medical Injury: Theory and Evidence" (1998) 67 U. Cin. L. Rev. 53 at 65 for a discussion of the WCB system as a model for medical injury reform.
[68] *Ibid.*
[69] *Ibid.* at 79.

awareness of OHS issues.[70] The agency is governed by a Council that has representatives from the provincial, federal and territorial governments, employers and workers.

The CCOHS acts as an accessible and credible source of information that gives meaning to the right to know. According to the CCOHS, person-to-person and on-line services have directly influenced how employers and employees approach safety concerns in the workplace.[71] According to their own reports, over 75 percent of CCOHS clients claim to have instituted changes in the workplace in part as a result of visiting CCOHS."[72]

[70] Canada, *Canadian Centre for Occupational Health and Safety Report of the Council: April 1, 2003 to March 31, 2004* (Ottawa: CCOHS, 2004) at 1, online: CCOHS < http://www.ccohs.ca/ccohs/reports/AnnualReport_0304.pdf>.
[71] *Ibid.* at 4.
[72] *Ibid.* at 1, 4.

Patient Safety Law:
From Silos to Systems

Appendix 3: Sector Reports
TRANSPORTATION

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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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Introduction

In many areas of the Canadian transportation industry, safety regulation is shifting from a prescriptive, command and control model to one that acknowledges transportation providers' primary responsibility "for day-to-day implementation of safety measures" and uses mechanisms to build a culture of safety in these operations.[1]

We provide a brief overview of safety concerns in transportation, the deregulation of the transport sector, and briefly discuss the similarities and differences between the health and transportation sectors. We then outline the current regulation of transportation safety in Canada. While there are four main sectors in the transportation industry in Canada (air, marine, ground and pipeline), for reasons of time, space, and utility, we will not provide a detailed analysis of all four. Therefore the last section of this appendix will focus on the legal instruments used to regulate safety in air and ground transportation sectors (rail and road). The regulatory frameworks, in whole or in part, that govern safety in these sectors may provide a model for health care.

Safety Concerns in Transportation

Since the invention of planes, trains, and motor vehicles, their safety has always been in question. There has always been some form of regulation by the state to mitigate and manage the very obvious risks associated with the technology.

From the 1930s onwards, when there were some spectacular aviation crashes, particularly that involving the Hindenberg, there was intense public scrutiny of crash investigations resulting in aviation investigators abandoning secrecy policies in respect of accident investigations and establishing a culture of open investigations.[2] Reasonably open investigations have been a characteristic of the transport sector for a number of years.

Internationally, a series of major tragedies in aviation, in rail and in commercial transport rocked the transportation sectors in western countries in the 1970s and 1980s and resulted in significant media scrutiny, public concern, and consequently political attention. These tragedies included:

- the deaths of 583 people at an airport in the Canary Islands in 1977 after two planes collided on the tarmac;

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[1] Transport Canada, *Straight Ahead – A Vision for Transportation in Canada*, at 69-70, online: Transport Canada < http://www.tc.gc.ca/publications/straightahead/includes/printable.asp?lang=en > [*Straight Ahead – A Vision for Transportation in Canada*].

[2] Australian Council for Safety and Quality in Health Care, "Setting the Human Factor Standards for Health Care: Do lessons from Aviation Apply? A Report on the Human Factors in Health Care" (Workshop at the 6th International Australian Aviation Psychology Symposium, December 2003) (Canberra: Australian Council for Safety and Quality in Health Care, 2004).

- the loss of 257 people after a plane flew into Mt. Erebus in Antarctica in 1979;
- the deaths of 35 people at Clapham station in London, England after three rush-hour commuter trains collided in 1988;
- the deaths of 23 people at Hinton in Canada after a freight train collided with a passenger train in 1986.

At the same time, other significant transport or industrial accidents contributed to the perception that there was a need to strengthen safety requirements for the transportation sector and other high risk industries including:

- the Piper Alpha disaster where an off-shore oil platform in the North Sea exploded and burnt with the loss of 167 lives in 1988
- the sinking of the Herald of Free Enterprise in the English Channel in 1987 with the loss of 193 lives after its bow doors failed to close and it took on water.
- the leaking of poison gas from the Union Carbine Chemical Factory in Bhopal, India, in 1984 - about 20,000 people are thought to have died from the effects of the gas to date, with around 110,000 still suffering.
- the meltdown of a reactor at the Chernobyl nuclear power plant in the then U.S.S.R. in 1986 which resulted in an unknown number of deaths and the spread of a radioactive plume across Europe.

As a result, there was a re-examination of safety related issues in the transportation sector, at regulatory and policy and practice levels. The New Zealand Royal Commission that investigated the Erebus crash was particularly significant in terms of the impact that it had on accident investigation processes in the transport sector subsequent to the report. The Commission moved away from a somewhat pro forma conclusion that the crash was due to pilot error, and conducted a review of the systemic factors that contributed to the crash. It directly attributed responsibility for the crash to "incompetent administrative airline procedures which made the mistake possible."[3] This was highly influential in broadening the focus of investigations to include human factors analysis.

Safety has, however, also been a matter of internal concern in the transportation sector. In many cases, if there is a serious accident the pilot, train-driver or truck-driver will directly experience the adverse event i.e. will be injured or die. This, in theory at least, concentrates the mind of the majority on safety and makes them more receptive to safety measures and more inclined to develop a safety culture. It also means that safety in transportation sectors is integrally connected with occupational health and safety, mechanisms discussed in another appendix to this report.

Deregulation

[3] *Ibid.* at 10.

In the wake of deregulation in the transport sectors in many nations, notably the U.S.,[4] Canada underwent a similar process of regulatory reform to allow for greater commercial freedom. The federal government removed many of the economic restrictions formerly placed on the industry and opened up sectors of the industry to domestic and international competitive market forces. In 1987, Parliament amended the *National Transportation Act* of 1967 (NTA) and the associated *Motor Vehicle Transport Act* of 1954 (MVTA). The 1987 amendments to the NTA made competition the "principle mediation force" of the transportation industry,[5] demonstrated by increased deregulation of the air and trucking industries. The NTA also introduced pro-competitive rail measures.[6]

The *Canada Transportation Act 1996* (CTA) replaced the NTA. The CTA further deregulated and commercialized the industry, responding to the view that in spite of the regulatory reforms of the 1980s, legislative restrictions remained too onerous.[7] The CTA also introduced policy directives on safety.[8] The CTA stresses the importance of "harmonized federal and provincial regulatory approaches" to ensure, among other things, that "the national transportation system meets the highest practicable safety standards," and that "competition and market forces are, whenever possible, the prime agents in providing viable and effective transportation services."[9]

With economic efficiency and safety as the primary goals of the transportation industry, concerns are often raised about how to balance these seemingly competing goals. Early critics of deregulation warned that training and retraining programs would be compromised, particularly in companies under financial strain, and that there would be decreased investments in maintenance. Critics also warned that deregulation might compromise the rate at which companies replace old, outdated equipment.[10] Other criticisms included heightened worry that financial pressure could lead to the adoption of unsafe working procedures. For example, speeding and sleep deprivation in the trucking sector could become more systemic, particularly in companies where employees were

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[4] Deregulation in North America was first introduced in the U.S. with the enactment of the *Airline Deregulation Act of 1978* and the *Motor Carrier Regulatory Reform and Modernization Act of 1980.* Regulatory reform in the airline, rail and trucking industries promoted greater freedom of entry into the industries and into (or out of) particular markets, as well as greater freedom of rate making. See Leon N. Moses & Ian Savage, *Transportation Safety in an Age of Deregulation* (New York: Oxford U.P., 1989) at 3 [Moses].

[5] Canada Transportation Act Review Panel, *Canada Transportation Act Review: Vision and Balance* (Ottawa: Minister of Public Works and Government Services, Canada, 2001) at 7.

[6] *Ibid.*

[7] *Ibid.* at 8.

[8] *Ibid.* at 20.

[9] R.S.C. 1996, c. C-10, ss. 5(a)-(b). In 2001 a comprehensive review of the CTA was conducted wherein the review panel makes a point of stating that competitive access is not a "non-regulatory" solution. The panel acknowledges that "extensive regulation is required to oversee conditions of access and the price, to monitor safety and operations, and to settle disputes". See Canada Transportation Act Review Panel, *Canada Transportation Act Review: Vision and Balance* (Ottawa: Minister of Public Works and Government Services, Canada, 2001) [*Canada Transportation Act Review: Vision and Balance*].

[10] Moses, *supra* note 4 at 6.

pushed to meet tight deadlines.[11] There is debate over whether or not transportation objectives can be met within a system that relies on market forces.[12]

The tension between economic goals compatible with deregulation and social concerns that rely on governmental regulation remains unresolved.[13] The largest union representing Canadian flight attendants argued to a Senate Subcommittee on Transportation Safety that economic deregulation has impacted negatively on aviation safety. However, evidence presented by Transport Canada stated that "the safety data does not show any link to deregulation and reduced safety. In fact the safety record has steadily improved since deregulation."[14] The Committee itself felt that Transport Canada's safety oversight should not be further diminished in order to "ensure no party is sacrificing safety on the altar of the economic bottom line." Following the introduction of regulatory reforms in Canada, the federal government has augmented its focus on safety in the transportation industry and Transport Canada states that "safety and security have remained central objectives of national transportation policy." [15]

Healthcare and Transportation

Differences in context are crucial when examining frameworks and instruments used in one sector with a view to adoption in an unrelated sector. The assertion that what works in one sector is automatically transferable to another sector cannot be accepted uncritically. Commentators disagree on exactly the degree of convergence between the transportation and health sectors. Much of the analysis of similarities and differences focuses on the aviation sector, the sector with initiatives, regulatory and otherwise, identified by researchers and by the patient safety movement as having the most promise for adoption into the health sector. However, some comments may be equally, if not more, applicable to other transportation modalities such as road and railways.

Both sectors, attracted early regulatory scrutiny, to a greater or lesser extent, because of the risks each posed to the health and safety of the public. Perhaps correspondingly, one historic commonality in healthcare and in the transportation sectors was a tendency in both industries when something went wrong to ask "who is wrong?" not "what is wrong", and a tendency to blame and penalize individuals for acts that, when placed in context, have a significant systemic component.

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[11] *Ibid.*
[12] *Canada Transportation Act Review: Vision and Balance*, *supra* note 9 at 13.
[13] Jason S. Kelley, "Privatization of Transportation in Developed Nations" (1996) 48 Admin. L. Rev. 545 at 557.
[14] Standing Senate Committee on Transport and Communications, *Report on Air Safety and Security*: *Report of the Subcommittee on Transportation Safety of the Standing Senate Committee on Transport and Communications* (Ottawa: Government of Canada, 2000) at c. 2.
[15] *Straight Ahead – A Vision for Transportation in Canada*, *supra* note 1 at c. 1.

In all, with the exception of road transport, individuals tend to work in small teams that are hierarchical in nature, hierarchy often discouraging contributions by subordinates. All of these sectors are burdened by individual expectations that individuals must perform as 'iron-men' or 'supermen'. Thus, a culture where there is open and valued communication within work teams and where limits to human performance are recognized and respected are crucial to achieving safety.

In healthcare and in transportation there is a constant trade-off between safety, efficiency (including cost), and the quality and reliability of the services in the context of systems with limited capacities.[16]

Some commentators strongly argue that aviation is very similar to healthcare or as one supporter puts it "share a staggering commonality".[17] Aviation and healthcare are arguably "sharp end" industries, in which a complex system of knowledge and expertise, technology, performance history and invested capital can be put at risk by an individual working at the sharp end.[18] Or in other words, a human error in aviation can result in the loss of a plane and all on board it. Similarly, an error in medicine may result in the death or significant injury of a patient. Critics suggest that this alleged similarity is an oversimplification of a complex issue. There is a substantial difference between circumstances in aviation when a safety issue will see many people will die, likely including the pilots, and a safety issue in healthcare where likely only one person will die. Critics also suggest that health providers see death on a regular basis and do not always know what, if anything contributed to the death, so may not be as affected by it.[19] If the pilots themselves are likely to die if there is a safety issue they are likely to be more focused on safety, in their own self-interest if for no other reason. It also then becomes an issue of passenger and worker safety, involving overlaps with occupational safety and health regulation.

Nance quotes the following definition which he states seems to fit both industries:

> Highly trained, highly motivated professionals working in a real-time, high pressure environment, using very sophisticated implements and tools under great public and regulatory scrutiny, where the penalties for failure are potentially very great both in human and monetary terms.[20]

While there may appear to be broad similarities (especially between aviation and healthcare), critics suggest that a closer examination shows more important differences between the sectors. Randell, for example, notes that in aviation pilots are confined in a

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[16] Trudi Farrington-Darby, Laura Pickup & John R. Wilson, "Safety Culture in Railway Maintenance" (2005) 43 Safety Science 39 at 43.
[17] John Nance, "Admitting Imperfection: Revelations from the Cockpit for the World of Medicine" in Barbara Youngberg & Martin Hatlie, eds., *The Patient Safety Handbook* (Sudbery, MA: Jones & Bartlett, 2004) at 187 [Nance].
[18] Dr. James Reason coined the term sharp end. See Nance, *ibid*.
[19] R. Randell, "Medicine and Aviation: A Review of the Comparison" (2003) 42:4 Methods Inf. Med. 433 [Randell].
[20] Nance, *supra* note 17 at 194.

small space with a standard layout and often work regularly with the same small team. In healthcare, it is common to provide treatment and care in varying environments with no standardized layout, standardized equipment, or standard use of that equipment. It is also common that teams of healthcare providers are larger, more diffuse, and require more integration. In addition, in aviation pilots interface with technology, with the only common external variable being the weather. In healthcare, even when technology is used, the health provider is interfacing with technology and with a patient whose needs may be complex, changing, and uncertain.[21]

It is also easier for health providers to hide unsafe care and, because of complex systems and human resilience, for small mistakes to relatively rarely propagate or culminate in major tragedies. In short, healthcare is a very diffuse or loosely coupled system. In contrast, a small error in aviation is more likely to result in a major tragedy because aviation is a highly coupled system.[22]

There are even fewer similarities on the face of it between the railway and healthcare sectors. Railways focus on management and not design, are distributed rather than centralized, are able to be considered as parts rather than a whole and are heavily dependent on human factors as well as technical aspects. In addition, railway safety issues have both internal and external accident consequences and are subject to external scrutiny. At this generic level, there are some similarities. However, railway systems are reasonably simple rather than complex and are reasonably transparent in that it is easier to determine what occurred.[23] There are even fewer similarities between the commercial vehicle sector and healthcare.

Jurisdiction

Both the federal and provincial governments regulate safety in the transportation sector. Aviation is a federal responsibility; railways fall under both federal and provincial jurisdiction (some companies operate short-line tracks that only operate within one province and accordingly are a provincial responsibility).[24] Roads and road safety are primarily a provincial and municipal responsibility, but the federal government has authority over inter-provincial commercial transport providers and regulating the safety aspects of the design and manufacture of vehicles.[25]

Federal Regulation

[21] Randell, *supra* note 19.
[22] *Ibid.*
[23] David Elms, "Rail Safety" (2001) 74 Reliability Engineering & System Safety 291.
[24] *Canada Transportation Act Review: Vision and Balance*, *supra* note 9 at 14.
[25] *Attorney-General for Ontario v. Israel Winner*, [1954] A.C. 541 (P.C.) [*Winner*].

As part of the deregulatory process, government recognized the conflict of interests posed by integrated transport agencies that regulated safety and economic issues and conducted investigations into possible violations by regulators and the regulated. Accordingly, three key transport related institutions were established at the federal level: Transport Canada, the Canadian Transportation Agency and the Transportation Safety Board of Canada.

Transport Canada

Transport Canada (T.C.) implements the federal government's policy on transportation safety.[26] Its mission is "to further advance the safety and security of an efficient, accessible, and sustainable transportation system."[27] Safety is T.C.'s "top priority" and is promoted through "rulemaking" (i.e. setting regulations, standards and policies), "oversight" (i.e. issuing licenses, certificates, registrations and permits; monitoring the transportation system's performance and compliance, conducting inspections and other enforcement measures), and "outreach" (i.e. through public awareness campaigns).[28]

The bodies that govern and set much of T.C. safety policy are: the Canadian Council of Motor Transport Administrators, the Transportation of Dangerous Goods Advisory Council, the Canadian Marine Advisory Council, and the Civil Aviation Regulations Advisory Council. Federally, T.C. works in partnership with the Transportation Safety Board, the Canadian Transportation Agency, and NAV Canada.[29] They also work with various international organizations to harmonize "transportation rules, standards and regulations to facilitate trade while maintaining high levels of safety." [30]

One of T.C.'s central policy goals is to build a "safety culture" by encouraging alternatives to traditional prescriptive and policing approaches to regulation. Where it is required to regulate, they focus on the safety objective rather than on the process by which it is to be achieved.[31] It also emphasizes the importance of collecting accurate

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[26] Transport Canada, Minister of Public Works and Government Services, *Looking to the New Millennium: Transport Canada 2001-2004 Business Plan – An Update* (Ottawa: Canadian Government Publishing, Minister of Public Works and Government Services Canada, 2001) at 5 [*Looking to the New Millennium*].

[27] *Ibid.* at 9; Transport Canada, Minister of Public Works and Government Services, *Transport Canada's Strategic Plan for Transportation Safety and Security* (Ottawa: Canadian Government Publishing, 1999) at 3 [*Transport Canada's Strategic Plan for Transportation Safety and Security*].

[28] Transport Canada, *On The Move—Keeping Canadians Safe* (Brochure) (Ottawa: Canadian Government Publishing, 2004) at 1 [*On The Move—Keeping Canadians Safe*].

[29] NAV Canada is "a private, non-share capital corporation that owns and operates Canada's civil air navigation service (ANS)." See NAV Canada, "About Us," online: NAV Canada <http://www.navcanada.ca/NavCanada.asp?Language=en&Content=ContentDefinitionFiles\AboutUs\default.xml>.

[30] The main international organizations they work with are: The International Civil Aviation Organization, The International Marine Organization, The UN World Forum for the Harmonization of Vehicle, Regulations, NAFTA committees and sub-committees on Safety Issues, Organization for Economic Cooperation and Development (OECD), APEC Transportation Working Group, The Organization of American States-Inter-American Committee of Ports, and The Western Hemispheric Transportation initiative. See *Looking to the New Millennium*, *supra* note 26 at 11.

[31] *Transport Canada's Strategic Plan for Transportation Safety and Security*, supra note 27 at 6.

safety data on which to base its policy decisions and measure their impact.[32] (The various reporting methods for the collection of safety information in Canada are discussed in more detail in the latter sections of this report.)

T.C. is involved in transportation safety in each sector as follows:

- **Aviation:** T.C. establishes regulations for the safe manufacture, operation, and maintenance of aircraft, sets training and licensing standards for pilots and requires the implementation of safety management systems. Compliance activities include a program of inspections, audits, and other monitoring activities.[33]
- **Rail:** T.C. administers "programs and services to support a clear and innovative regulatory regime" (including regulations in relation to the safety of operations, infrastructure, and people, as well as requiring the implementation of safety management systems) and promotes other public awareness campaigns to improve railway crossings, eliminate unsafe crossings and educate minors on the dangers of crossings.[34]
- **Marine:** T.C. regulates safety for both private and commercial vessels, inspects domestic and foreign vessels in Canadian waters, as well as offshore rigs so that safety standards are met, and T.C. overseas the certification of commercial officers and crews.[35]
- **Road:** T.C. sets standards for vehicles, tests vehicles and equipment, and investigates manufacturing defects. T.C. also regulates the safety of the inter-provincial commercial vehicle sector.[36]
- **Transportation of Dangerous Goods:** T.C. regulates safe transport and operates emergency response personnel.[37]

The Canada Transportation Agency

The Canada Transportation Agency (CTA) was established under s. 6 of the NTA of 1987, following the government decision to deregulate various sectors of the transportation industry. The CTA is responsible for implementing the federal government's transportation policy on economic matters, outlined in the *Canada Transportation Act 1996*. The policy primarily relates to commerce, however, it also includes a statement on safety.

The Transportation Safety Board of Canada

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[32] *Ibid.* at 4.
[33] Transport Canada, "Aviation Safety in Canada: A Shared Responsibility," online: Transport Canada <http://www.T.C..gc.ca/mediaroom/backgrounders/b01-A100.htm>.
[34] *On The Move—Keeping Canadians Safe*, *supra* note 28 at 6.
[35] *Ibid.* at 8.
[36] *Ibid.* at 10.
[37] *Ibid.* at 11.

After a Congressional investigation into the conduct of an investigation into a serious plane crash conducted by the U.S. Department of Transport, it was determined that to encourage public confidence in transportation accident investigation an investigation agency must be independent, objective and free from conflicts of interest.[38] A conflict of interest arises when a government body regulates, enforces, provides or operates transportation activities, and in turn investigates the failures associated with its regulations or operations. Agencies were also often a party to litigation in the transport sector. This conflict meant that there is a risk, or at least a perception, that investigations were incomplete due to that conflict of interest. In Canada from the late 1960's the Canadian Bar Association and the Canadian Air Line Pilots Association raised the potential for conflict in the investigation of aviation incidents.[39] A Royal Commission of Inquiry on Aviation Safety in Canada, chaired by Justice Dubin, in 1981 recommended the creation of an independent tribunal to investigation accidents in aviation.[40] In 1983, the Federal Parliament adopted the *Canadian Aviation Safety Board Act*. The Act created the Canadian Aviation Safety Board (CASB) to investigate aviation occurrences.

In 1989, the Parliament dismantled CASB and created a new Board. The Transportation Safety Board of Canada (TSB) is an independent agency created by s. 4 of the *Canadian Transportation Accident Investigation and Safety Board Act*, 1989 (CTAISBA). It is truly independent in that it reports to Parliament through the President of the Queen's Privy Council for Canada and is separate from other agencies and departments.[41] The TSB's remit includes all aspects of transportation safety, at least those sectors of transportation regulated at the federal level (aviation, rail, pipelines, and marine – it does not include road safety, except as it impinges upon one of the other sectors, e.g. safety at railway crossings).

The purpose of the TSB is to advance transportation safety by conducting independent investigations into safety related occurrences in marine, pipeline, rail, and air modes of transportation to make findings as to the causes and contributing factors. 'Occurrences' are essentially accidents or incidents associated with the operation of a mode of transportation or situations or conditions relating to a mode of transport that if left unattended may induce an accident or incident. The Board is also supposed to identify safety deficiencies, make recommendations designed to eliminate or reduce deficiencies and report publicly on the findings of its investigation.[42] The legislation is clear that the Board is not to assign fault, or to determine criminal or civil liability, but also must not

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[38] In 1935 a plane crashed in the U.S. killing a U.S. Senator. Congress decided to conduct its own investigation in parallel with the 'official' Bureau of Air Commerce inquiry. Congress concluded the the Department of Commerce and the Bureau worked too closely with commercial airlines and aircraft manufacturers to be objective and therefore were reluctant to admit that accidents may have been related to their own rules and procedures.

[39] Bernard Deschênes, "The Canadian Aviation Safety Board: Experiences in International Co-Operation and Adaptation" (1987) 12 Ann. Air & Sp. L. 3 at 3 [Deschênes].

[40] Canada, Commission of Inquiry on Aviation Safety, *Report of the Commission of Inquiry on Aviation Safety* (Ottawa: Supply & Services Canada, 1981) (Commissioner: Justice Charles L. Dubin).

[41] Transportation Safety Board, *Annual Report to Parliament 2003-2004* (Ottawa: Government of Canada, 2004).

[42] *Canadian Transportation Accident Investigation and Safety Board Act*, R.S.C. 1989, c. 3, s. 7 [*Canadian Transportation Accident Investigation and Safety Board Act*].

refrain from making a full report because such liability might be inferred from its findings.[43]

Under s. 8 of the CTAISBA, the TSB has the power to make policies in relation to classes of occurrences that will be the subject of investigation and the conduct of the investigation of "occurrences" in the various transportation sectors. The TSB must take all reasonable measures to ensure that the investigation processes it follows comply with any international agreements or conventions to which Canada is a party (i.e. Annex 13 of the *Convention on International Civil Aviation* (Aircraft Accident and Incident Investigation[44])) and the investigation procedures and practices of Coroners in the provinces. In its *Occurrence Classification Policy* the Board's criteria for investigation is whether or not an investigation is likely to lead to a reduction in risk to persons, property or the environment.[45] About 4,000 occurrences are reported each year.

While the TSB may choose to investigate any transport related occurrence that fits within its policy, it also must investigate transport occurrences when requested to do so by the Governor in Council. It may investigate when requested by a department, lieutenant governor in council of a province or the Commissioner of the North West Territories, or Nunavut, or the Commissioner of the Yukon with the consent of the executive council of that territory, provided the provinces/territories agree to defray reasonable costs. The legislation specifies that no department, other than National Defence, may commence an investigation into the causes and contributing factors of a transport related occurrence if the TSB is investigating it or if the TSB proposes to investigate it. The TSB may also enter into agreements to investigate occurrences that fall within provincial jurisdiction, again on the condition that expenses are defrayed. If, during the course of an investigation, the Board considers that a public inquiry is necessary then the Chairperson of the TSB may order a public inquiry. Public inquiries are held by way of a public hearing, with the assistance of a technical panel.

The CTAISBA also establishes Directors of Investigation for each sector. Directors are granted exclusive authority to direct the conduct of investigations on behalf of the Board, according to TSB policy.[46] This was so that the Board might be in a truly impartial position when issuing a report, through ensuring a clear separation between investigators and the Board.[47]

TSB investigators have search and seizure powers, powers to limit or prohibit access to an area, require attendance of a witness or evidence under oath, require medical examinations, order an autopsy, and require the provision of information by a medical practitioner.

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[43] *Ibid.* at s. 7(2).
[44] International Civil Aviation organization, *Convention on International Civil Aviation: Annexes 1-18* online: ICAO <http://www.icao.int/cgi/goto_m.pl?icaonet/anx/info/annexes_booklet_en.pdf>.
[45] Transportation Safety Board of Canada, "Planning, Reporting and Accountability Structure", online: TSB <http://www.tsb.gc.ca/en/publications/financial/finished_pras97.asp>.
[46] *Canadian Transportation Accident Investigation and Safety Board Act, supra* note 42 at s. 10.
[47] Deschênes, *supra* note 39 at 5.

Following investigations, the TSB must "prepare and make available to the public a report on its findings, including any safety deficiencies that it has identified and any recommendations that it considers appropriate in the interests of transportation safety."[48] The TSB is also required to provide interested parties with written notification of their findings including the causes and contributing factors of the transportation occurrence, any safety deficiencies, and any recommendations that require "urgent action."[49] As a matter of practice, the TSB shares safety information throughout the investigation/inquiry to the public and other interested parties.[50] It also publishes safety digests for each sector, setting out safety lessons learned as a result of TSB inquiries.[51] However, it is important to note that the TSB can only issue recommendations. Those affected by the recommendations have a specified period of time to respond to the TSB to explain their proposed course of action in response to the recommendations. There is some concern that the reflex of the TSB is to suggest more regulations, which is contrary to the ethos of T.C., which is moving from command and control governance modes to an integrated governance model.[52] There is also a sense of hesitation about how adequately the TSB is adapting to newer modes of human factors analysis adopted as part of the regulatory frameworks with aviation and rail.[53]

The TSB may pass regulations that require mandatory or voluntary reporting of occurrences, and use the information gathered by these reports as is necessary in the interest of transportation safety.[54] The *Transportation Safety Board Regulations* establishes mandatory reporting requirements for specific types of incidents for each specific sector. The specific types of incidents or accidents that must be reported are clearly set out in section 2 of the Regulations. So the individuals and companies involved in an accident or incident must report certain specified information as soon and as quickly as possible to the Board. Within thirty days, they must report additional specified information to the Board.[55] The regulations also allow for voluntary reporting where any person with knowledge of an accident, incident, or special situation associated with the transport activities subject to regulation may report to the Board. The Board can set up a

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[48] *Canadian Transportation Accident Investigation and Safety Board Act*, *supra* note 42 at s. 24(1).

[49] *Canadian Transportation Accident Investigation and Safety Board Act*, *supra* note 42. See Ewa Swiecicki, "Liability of the Canadian Government for the Negligent Enforcement of Aviation Safety Legislation" (1993) 18 Ann. Air & Sp. L. 275 at 275-308 for an in-depth analysis of tort liability as it applies to public authorities.

[50] Transportation Safety Board of Canada, "Investigation Process", online: TSB <http://www.tsb.gc.ca/en/investigation_process/access.asp>.

[51] Available online: Transportation Safety Board of Canada <http://www.tsb.gc.ca/en/publications/reflexions/rail/index.asp>.

[52] Discussion with Civil Aviation representative.

[53] *Ibid*.

[54] *Canadian Transportation Accident Investigation and Safety Board Act*, *supra* note 42 at s. 31.

[55] *Transportation Safety Board Regulations*, S.O.R./92-446, s. 7 reads: "Any person having knowledge of any accident, incident or special situation associated with the operation of a ship, rolling stock, commodity pipeline or aircraft may report to the Board any information that the person believes is relevant." "The Board may establish a confidential reporting unit that shall have exclusive authority to receive and examine in confidence any verbal or written report made pursuant to section 7" [*Transportation Safety Board Regulations*].

confidential reporting system for voluntary reports.[56] It has set up a system called SECURITAS. A person who wishes to file a report must provide their name and contact information. After TSB staff review the record identifying information is deleted. The regulations also specify that identifying information cannot be disclosed without the written consent of the individual concerned.

Section 28(2) of the CTAISBA protects on-board recordings, section 29(6) protects communication records, and section 30(7) protects statements from use as evidence in legal, disciplinary, or other proceedings (except for prosecutions for perjury, giving contradictory evidence, or obstruction). The TSB may access on-board recordings, communication records, and statements during its investigation and may authorize release to a Coroner. A court may order production when "the public interest in the proper administration of justice outweighs the importance of privilege" subject to whatever restrictions or conditions deemed appropriate. TSB investigators may not give evidence before any forum other than a Coroner, unless specially ordered by a court, but a member or investigator's opinion is not admissible in evidence in any legal, disciplinary, or other proceedings.

Aviation

Aviation is a highly regulated sector, governed by both international and national law. Philosophies of risk management in aviation safety[57] have undergone refinement and evolution during the past 100 years, from an initial focus on technological/operational factors, through a later emphasis on (individual) human factors, to finally culminate in a systemic, "organizational factors" approach to risk causation.[58]

International Regulation

The 1944 '*Chicago' Convention on International Civil Aviation*[59] governs civil aviation safety worldwide. The Convention has 188 member states and establishes the International Civil Aviation Organization (ICAO) (a branch of the UN), as an advisory

[56] *Ibid.* at s. 8; Transportation Safety Board of Canada, "Securitas – Confidential Reporting," online: TSB <http://www.tsb.gc.ca/en/securitas/securitas.asp#confidentiality>.

[57] But see Evan P. Singer "Recent Developments in Aviation Safety: Proposals to Reduce the Fatal Accident Rate and the Debate Over Data Protection" (2002) 67 J. Air L. & Commerce 499 at 503, where it is reported that the rate of aviation accidents has been 'flat' for past 20 years (1982-1994) at around 0.058 to 0.051/100,000 departures, but the rate has decreased in the U.S. and worldwide from1994-99 dropping from 0.051-0.018/100,000 departures.

[58] Samantha Sharif, "The Failure of Aviation Safety in New Zealand: An Examination of New Zealand's Implementation of its International Obligations Under Annex 13 of the Chicago Convention on International Civil Aviation" (2003) 68 J. Air L. & Commerce 339 at 340 [Sharif].

[59] *Convention on International Civil Aviation*, 7 December 1944, 15 U.N.T.S. 295, ICAO Doc 7300/6.

body to lay down international aviation rules.[60] Two bodies in the ICAO have legislative power: the Assembly of Member Nations and the Council (elected by the Assembly).[61]

The Convention also created Global safety standards (SARPS), listed in 18 Annexes. These Annexes are not considered part of the Convention and thus are only non-binding "soft law."[62] A major criticism of the Convention is that it and its SARP standards have traditionally had no enforcement mechanism. Despite the lack of enforcement, some think the Convention has had a positive effect on safety as all aircraft must undergo scheduled, periodic maintenance checks and all pilots must have regular, mandatory proficiency checks.[63] Nonetheless, some member countries have arranged bilateral treaties with each other to guarantee mutual aviation safety.[64]

National Regulation

Aviation safety in Canada is seen as a shared responsibility among everyone in the sector, including regulators, operators and manufacturers. The focus is on prevention, rather than punishment. The current trend in aviation safety is for the government to delegate the responsibility for the actual implementing and monitoring of safety programs to the private operators within the sector, while retaining authority over policy setting, regulation making, investigation and enforcement. [65]

The main national agencies involved in aviation safety are: Transport Canada, the Canadian Aviation Regulation Advisory Council (CARAC), and NAV CANADA. As well, the private companies play a major role in aviation safety. All of these groups work within the legislative framework of the *Aeronautics Act* and the *Canadian Aviation Regulations* (CAR).

Transport Canada sets the regulations and standards for training and currency or pilots, air traffic controller and aircraft maintenance engineers. They also regulate the safe operation, maintenance and manufacture of aircraft in Canada.[66]

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[60] Anthony J. Broderick & James Loos, "Government Aviation Safety Oversight— Trust, But Verify" (2002) 67 J. Air L. & Comm. 1035 at 1037.
[61] *Ibid.* at 1048.
[62] Michael Milde, "Aviation Safety and Security – Legal Management" (2004) 29 Ann. Air & Sp. L. 1 at 1.
[63] Michael B. Jennison, "The Chicago Convention and Safety After Fifty Years" (1995) 20 Ann. Air & Sp. L. at 283 at 286.
[64] Senerath D. Liyanage, "Aviation Safety Oversight Assessment" (1996) 21:2 Ann. Air & Sp. L. 235 at 256. See also Louis Gialloreto, "International Air Transport Regulation and Airline Efficiency – Is There a Link?" (1995) 20:1 Ann. Air & Sp. L. 459 at 459, who states that the bilateral system worked well to the 1970s but thereafter it needed and failed to evolve.
[65] Transport Canada, "Flight 2005 - A Civil Aviation Safety Framework for Canada (TP13521)," online: Transport Canada <http://www.tc.gc.ca/CivilAviation/flight2005/tp13521/menu.htm>.
[66] Transport Canada, "Aviation Safety in Canada: A Shared Responsibility," online: Transport Canada <http://www.tc.gc.ca/mediaroom/backgrounders/b01-A100.htm>.

CARAC is comprised of members from both the government and the aviation community. The non-governmental participants include air operators, aviation labour organizations, manufacturers, industry associations and groups representing the public. Their primary goal is to "assess and recommend changes to Canada's aviation regulations and standards through co-operative development activities."[67]

NAV Canada is a private, not-for-profit corporation that coordinates the safe and efficient movement of aircraft in both domestic and international airspace assigned to Canada. They provide services such as air traffic control, flight information, weather briefings, airport advisories and air navigation aids.[68]

Individual private players – airlines, manufacturers and maintenance companies - in the aviation sector play a significant role in regulating safety particularly since 2005 when government amended CARs.

In June 2005, the federal government amended the CARs to require holders of specified aviation certificates under CARS to appoint "accountable executives" and to implement Safety Management Systems (SMS) in their organizations.[69] This was part of a new regulatory approach instituted by Transport Canada which anticipates the need for aviation companies to adapt to emerging technology and the increased inter-connectedness of the 21st century while maintaining a high level of safety.[70] It also recognizes that traditional modes of regulation are resource intensive and may be impossible to sustain without great cost as the volume of aviation services continues to increase. Lastly, it recognizes that governance is a shared process, and that to achieve T.C.'s mission of developing and administering policies, regulations and programs for a safe, efficient and environmentally responsible transportation system is a shared responsibility between the regulator and regulates.[71]

T.C. notes that most experts in the field of organizational safety accept that most accidents are the result of a sequence of events where the human is the last link in a chain that lead to the incident. It is also recognizes that most links in the chain are controlled by the organization. Therefore, making the system requires action by an organization. T.C. determined that there are two components necessary to achieve this: a clearly identifiable individual must be designated as responsible for corporate decisions affecting safety and a systems approach to safety management must be implemented. An "accountable executive" is a person with financial and executive control over an entity, so someone with sufficient authority to ensure compliance with CARs and who is responsible for organizational compliance. The company must report the individual's name to the Minister and the individual must agree to accept responsibility for the creation and nurturing of a safety culture.

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[67] *Ibid.*
[68] *Ibid.*
[69] S.O.R./2005-173 [*Regulations Amending CARs*].
[70] Regulatory Impact Analysis Statement, C. Gaz. 2005. III. 1432 [Regulatory Impact Analysis Statement].
[71] *Ibid.* at 1444.

A systems approach is enabled through the requirement for institutions to enact a SMS. An SMS is a "documented process for managing risks that integrates operations and technical systems with the management of financial and human resources to ensure aviation safety or the safety of the public."[72] By requiring SMSs, the government hopes to increase industry accountability, create a positive and consistent safety culture, and help improve safety of all aviation operators.[73] T.C. says that this delegation has a "direct and positive impact by using existing personnel more effectively and efficiently – building a bigger team to get the work done and finding the most cost-effective way to achieve the required safety performance."[74] Safety management systems for air maintenance organizations or air operators which deal with certain types of aircraft are to include:

- a safety policy on which the system is based;
- a process for setting goals for the improvement of aviation safety and for measuring the attainment of those goals;
- a process for identifying hazards to aviation safety and for evaluating and managing the associated risks;
- a process for ensuring that personnel are trained and competent to the perform their duties;
- a process for the internal reporting and analyzing of hazards, incidents and accidents and for taking corrective actions to prevent their recurrence;
- a document containing all safety management system processes and a process for making personnel aware of their responsibilities with respect to them;
- a process for conducting periodic reviews or audits or the safety management system and reviews or audits for cause of the safety management system;
- any additional requirements for the safety management system that are prescribed under the regulations.[75]

Other types of services have slightly different requirements for what must be included into their safety management systems.[76]

There are also requirements for the development of quality assurance systems. Depending upon the type of certificate the organization holds it also must appoint a person to be responsible for maintenance control systems, maintenance, and operations manager, these positions report to the accountable executive but are responsible for enacting safety management systems and quality assurance programs.[77]

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[72] *Regulations Amending CARs*, *supra* note 69 at s. 1.
[73] Transport Canada, "Regulatory Amendments to Improve Aviation Safety Finalized," (15 June 2005), online: Transport Canada <http://www.tc.gc.ca/mediaroom/releases/nat/2005/05-h142e.htm>.
[74] Transport Canada, "A Layered Approach to Safety" (2005), online: Transport Canada <http://www.tc.gc.ca/mediaroom/backgrounders/b05-a002e.htm> [A Layered Approach to Safety].
[75] *Regulations Amending CARs*, *supra* note 69 at s. 107.03.
[76] See *ibid.* at ss. 573.31, 705.152.
[77] *Ibid.* at ss. 573.32, 705.153.

T.C.'s role in assessing the effectiveness of SMS systems is not to assess outcomes of the processes implemented by the companies but is rather to assess the effectiveness of the processes. It is also to provide a facilitation role between employer and unions, for without such co-operation in the transportation sector this initiative will not work.

SMS is to be implemented in a phased fashion starting with the larger components of the industry. Larger organizations are expected to get more benefit in terms of improved safety and cost savings. They have the resources and sophistication to implement. Smaller firms, by waiting will have the opportunity to learn from the experiences of larger firms and can implement scaled down solutions suitable to their size.

SMSs have been successfully implemented in the chemical industry in the United Kingdom and the accountable executive idea is being used in the marine sector in the U.K.[78] SMS has also been used in the rail sector in Canada for a number of years. Air Transat has also voluntarily used SMS systems for a number of years and reports fewer reactive and more proactive reports received and also savings of approximately $2 million per month.[79] From the experiences of Air Transat, T.C. argues that it seems that such systems can be effective and also cost-effective to implement.[80]

Licensing

Transport Canada has exclusive authority over licensing and testing of pilots, air traffic controllers and flight engineers. Standards for licensing and testing can be found in Part IV of the *Canadian Aviation Regulations* which include requirements of skill, experience and medical fitness.[81]

Monitoring Systems

Monitoring of safety in the aviation sector covers everything from equipment checks to verification of personnel qualifications. While Transport Canada is responsible for formal monitoring of safety, they delegate much of the responsibility to the private companies through the SMS. The SMS must be consistent with Transport Canada's policies and they are expected to have internal auditing and monitoring systems in place to ensure all internal, federal and international standards are being followed. Internal audits are a collaborative effort between all areas of management; they are constantly collecting and disseminating safety related information and making necessary changes in order to ensure

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[78] Transport Canada, "Safety Management Systems (SMS) – Frequently Asked Questions (FAQ)," online: Transport Canada <http://www.tc.gc.ca/civilaviation/SMS/FAQ/General/Q1.htm>.
[79] Michael Dilolo, "Safety Management Systems: A Way of Life," online: Transport Canada <http://www.tc.gc.ca/civilaviation/systemsafety/CASS/2004/PDF/Dilollo2.pdf>.
[80] Regulatory Impact Analysis Statement, *supra* note 70 at 1446.
[81] *Canadian Aviation Regulations*, SOR/96-433 [*Canadian Aviation Regulations*].

the maximum levels of safety at the minimum cost.[82] If a problem is discovered during an internal audit, the corporation is expected to take all reasonable steps to correct it, or risk opening themselves up to liability in negligence should an accident occur as a result.[83]

When operating under internal monitoring and auditing systems, each company is still subjected to formal audit and inspection by Transport Canada to ensure they are complying with all applicable safety regulations. Formal audits also assess the effectiveness of the SMS. Audits are normally conducted in cycles ranging from 6 to 36 months and inspections more frequently. Audit cycles are flexible depending on a company's history of compliance, risk indicators, and sophistication of internal auditing systems. When conducting the audits and inspections, officials do on-the-spot checks of equipment, systems, operations, documents and personnel qualifications.[84]

In addition to scheduled audits and inspections, officials also do incognito inspections of things such as airplane cabins to ensure that safety briefings are being done correctly and that required safety equipment is in place.[85]

Workplace Conditions

The CARs regulate the number of hours and conditions of employment for flight personnel. Pilots cannot work within 8 hours of consuming an alcoholic beverage, or while under the influence of drugs and alcohol.[86] Pilots cannot work more than 1200 hours/year, 300 hours/90 days or 120 hours/month.[87] In addition, they cannot work more that 14 hours in a 24 hour period and must have a rest period of 36 consecutive hours in 7 consecutive days or 3 consecutive days in a 17 day period.[88]

Research in the U.S. has attempted to analyze working hours in the transportation industry to better understand the relationship between shift-work and occupational health and safety. However, there are many reasons that such research is difficult to conduct. Working hours vary, and within the transportation industry, shifts tend to be irregular and unpredictable.[89] While there have been many studies conducted on night and shift work, analysts suggest that these studies do not adequately account for the irregular and unpredictable hours in the transportation industry where "the rate at which a schedule

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[82] R. Fenn, "The Principle of 'Foreseeability and Why a Safety Management System (SMS) is Important from a Legal Perspective" (Presentation to the Canadian Aviation Safety Seminar, April 2005) [unpublished].
[83] *Ibid.*
[84] A Layered Approach to Safety, *supra* note 74.
[85] *Ibid.*
[86] *Canadian Aviation Regulations*, *supra* note 81 at s. 602.03.
[87] *Ibid.* at s. 700.15.
[88] *Ibid.* at ss. 700.17, 700.19.
[89] Johannes Gärtner, "Analyzing Irregular Working Hours: Lessons Learned in the Development of RAS 1.0—The Representation and Analysis Software" (2004) Chronobiology Int. 1025 at 1026 [Gärtner].

may change, the degree of schedule predictability for employees, as well as control employees have on such changes" influence worker safety and health.[90] While the U.S. government has funded new software to analyze irregular shift-work, it is too early to predict its efficacy. [91] The outcome that analysts seem to predict is that this new software will define shift-length thresholds and be used as a preventative measure to reduce workplace incidents and accidents that are caused by worker fatigue. [92]

Reporting

When an aviation incident or accident occurs, the details[93] of the occurrence must be reported to the Transportation Safety Board. Some reportable occurrences include: accidents resulting in serious injury or death, engine failure, cabin depressurization and collisions.[94] Any person may also voluntarily report the details of an incident and their report is kept confidential.[95]

Transport Canada learns about less serious violations of the Canadian Aviation Regulations, not necessarily resulting in an immediate safety risk or incident, through routine inspections, field operations conducted by civil aviation inspectors, police reports, air traffic service personnel, aircraft accident investigations and public complaints. Reporting of these types of safety violations is strictly voluntary, however, in order to promote the shared responsibility for safety and the safety culture, individuals are encouraged to report incidents.[96]

According to each company's SMS, employees are encouraged to report safety related incidents internally so that they can be dealt with appropriately. To encourage employees to report incidents internally, the focus is on remedying the situation, rather than apportioning blame. For example, Air Transat uses an "immunity system" of reporting. They focus on the "why" rather than the "who" in order to encourage employees to report internally without the fear of facing punishment.[97]

Investigations

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[90] *Ibid.*
[91] *Ibid.*
[92] *Ibid.*
[93] *Transportation Safety Board Regulations*, *supra* note 55 at s. 6.
[94] *Ibid.* at s. 2(1).
[95] *Ibid.* at ss. 7-8.
[96] Transport Canada, "Aviation Enforcement Team: Here for Aviation Safety," online: Transport Canada <http://www.tc.gc.ca/civilaviation/RegServ/Enforcement/program/team.htm>.
[97] Canadian Aviation Executives Safety Network, *Safety Management Systems Assessment Guide* (Ottawa: Canadian Aviation Executives Safety Network, 2003) at 4 online Transport Canada: <http://www.tc.gc.ca/civilaviation/maintenence/Tp14326/menu.htm>.

The purpose of investigations in the aviation sector is to identify and remedy or remove deficiencies and not merely to assign blame or liability.[98] The way to do this is by analyzing not only major accidents but frequent, less serious 'incidents' as well,[99] which requires the cooperation of aviation professionals. Some argue that aviation prosecution is inversely related to aviation safety[100] and that protecting "full and frank communication" and the free flow of information are critical elements to the public interest[101] in improving commercial aviation safety.[102] If employees fear punishment from an investigation, they are less likely to be cooperative and to fully disclose the details of the incident.

In Canada, formal investigations following an occurrence are carried out by an Aviation Enforcement Inspector (AEI). The investigation involves a systematic collection of information and search for documentation relevant to the violation. Depending on the specific circumstances, investigators may be assisted by specifically skilled professionals from other branches of Transport Canada. Transport Canada and the RCMP may also conduct their own joint investigations.[103]

Transport Canada is currently working towards a system that would allow private companies to determine violations and propose corrective measures without the need for formal investigations. If a company with a valid SMS commits a safety violation that is not deliberate, they would report it to Transport Canada. They would then be given time to correct the violation and prevent it from happening again before a full-scale investigation would be conducted by an AEI. This approach will help to further nurture the "safety culture" whereby employees will voluntarily report violations without fear of punitive actions or intrusive investigations. After the internal investigation and corrective

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[98] Samantha Sharif, "The Failure of Aviation Safety in New Zealand: An Examination of New Zealand's Implementation of its International Obligations Under Annex 13 of the Chicago Convention on International Civil Aviation" (2003) 68 J. Air L. & Com. 339 at 344.

[99] Samantha Sharif, "The Failure of Aviation Safety in New Zealand: An Examination of New Zealand's Implementation of its International Obligations Under Annex 13 of the Chicago Convention on International Civil Aviation" (2003) 68 J. Air L. & Com. 339 at 356.

[100] Samantha Sharif, "The Failure of Aviation Safety in New Zealand: An Examination of New Zealand's Implementation of its International Obligations Under Annex 13 of the Chicago Convention on International Civil Aviation" (2003) 68 J. Air L. & Com. 339 at 351.

[101] See Samantha Sharif, "The Failure of Aviation Safety in New Zealand: An Examination of New Zealand's Implementation of its International Obligations Under Annex 13 of the Chicago Convention on International Civil Aviation" (2003) 68 J. Air L. & Com. 339 at 344 where on air investigator stated: "given the choice between a better chance to arrive safely at the other end or to pillory the pilot, most would choose the former."

[102] Sharif, *supra* note 58 at 347; National Transportation Safety Board Bar Association, Select Committee on Aviation Public Policy, "Aviation Professionals and the Treat of Criminal Liability – How Do We Maximize Aviation Safety?" (2002) 67 J. Air L. & Com. 875 at 880, 901; Evan P. Singer "Recent Developments in Aviation Safety: Proposals to Reduce the Fatal Accident Rate and the Debate Over Data Protection" (2002) 67 J. Air L. & Commerce 499 at 542-43.

[103] *Ibid.*

measures, Transport Canada would evaluate their solutions and, if suitable, no further investigative action would be taken. [104]

Remedies

Once an investigation has taken place and it is determined that a violation occurred, the Regional Manager of Aviation Enforcement (RMAE) will receive a report of the investigation and decide whether to proceed judicially or administratively. "Firmness and fairness" define how enforcement will proceed; public safety and economic consequences are also considered.[105] In determining a remedy, the focus will be on deterrence rather than punishment.

Judicial action is only applicable to a few provisions of the *Aeronautics Act* and CARs and would involve the prosecution of the offender in criminal courts. Administrative action covers all other offenses and could include oral counseling, suspension of licenses or certifications and fines.[106] If a corporation or an individual is charged with a safety infraction following an investigation, their names are published in the Transport Canada website along with a summary of the offense and resulting sanction.[107]

Railway

Railway accidents were frequent as railways developed. Accordingly, systems had to be developed to address the following issues:[108]

- good control of train movement
- fitness of vehicles and tracks
- human factors and culture
- interaction with the public i.e. road crossing points, public access points to tracks.

Today, railway accidents are thought to be less frequent. In 2003-2004 a total of 1030 rail accidents were reported to the TSB. Rail related fatalities reached a 21 year low of 79 in 2003. However, the quality of the data surrounding safety in rail is not good as it is dependent upon what is mandatorily (parameters proscribed by legislation) or voluntarily reported to the TSB.

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[104] Transport Canada, "Safety Management Systems/Aviation Enforcement Safety Management Systems Policy and Procedures," online: Transport Canada <http://www.tc.gc.ca/civilaviation/sms/infor/oct2005/1367799.htm>.
[105] Transport Canada, "About Aviation Enforcement" online: Transport Canada <http://www.tc.gc.ca/civilaviation/sms/infor/oct2005/1367799.htm>.
[106] *Ibid.*
[107] A Layered Approach to Safety, *supra* note 74.
[108] Elms, *supra* note 23.

Railway Safety in Canada is governed by the *Railway Safety Act 1989.*[109] The Act came into force as a result of the Hinton and Mississauga Inquiries into two significant railway incidents. The Act gives direct jurisdiction over safety matters to the Minister of Transport and defines the scope of his/her authority to ensure public safety in relation to the operation and management of railways under federal jurisdiction. The objectives of the Act are to:

(a) promote and provide for the safety of the public and personnel, and the protection of property and the environment, in the operation of railways;
(b) encourage the collaboration and participation of interested parties in improving railway safety;
(c) recognize the responsibility of railway companies in ensuring the safety of their operations; and
(d) facilitate a modern, flexible and efficient regulatory scheme that will ensure the continuing enhancement of railway safety.[110]

The Act was further amended in 1999 after a five year statutory review, an election and a serious incident involving a VIA passenger train in Biggar, Saskatchewan. The amendments provided for a more modern regulatory regime that includes the introduction of safety management systems, the use of audits to verify compliance, performance indicators to verify safety and compliance and consultation with stakeholders.

The Act grants the Minister of Transport authority to issue emergency directives preventing the use of equipment or works that pose an immediate threat to public safety.[111]

A key safety area for railways is the fitness of vehicles, tracks, and rail bridges. Section 7 gives the Governor–in-Council the authority to make safety regulations governing the construction or alteration of railway works (such as signaling systems). The Minister may also order a railway company to formulate engineering standards which may embrace physical standards and performance standards. Ministerial approval is required for work that will not be conducted according to engineering standards. Section 11 states that "all the engineering work relating to railway works, including design, construction, evaluation or alteration, shall be done in accordance with sound engineering principles. A professional engineer shall take responsibility for the engineering work." Professional engineers are obligated to protect public health, safety, and welfare. No consultation is required for the formulation of standards.

Section 18(1) grants the Governor-in-Council the power to make regulations: "respecting the operation or maintenance of line works, and the design, construction, alteration, operation and maintenance of railway equipment, which regulations may embrace, among other things, performance standards". The Minister can also order a railway company to file safety or security rules for approval. The company must make the rules

[109] R.S.C. 1985 (4th Supp.), c. 32 [*Railway Safety Act*].
[110] *Ibid.* at s. 3.
[111] *Ibid.* at s. 33.

in consultation with every relevant group that is likely to be affected by the rules. The railway companies, as part of the filing process, must make the Minister aware of the views of the relevant interested groups. The Minister must consider whether the rules are conducive to rail safety and either grant approval or not. The Minister can formulate rules on behalf of the company if it is unwilling or unable to do so. Railways companies may also propose rules on their own initiative. The Minister must also ensure that rules applying to a particular company are as consistent as possible with other rules dealing with other companies. A company can apply for an exemption from a rule and it can be granted if it is in the public interest and not likely to impact upon safety. A rule formulated pursuant to these sections, once approved by the Minister, has the status of a regulation.

The Governor-in-Council may also make regulations in regard to activities on lands adjacent to railways that might threaten railway safety operations.

Human Factors and Culture

Section 18(1) grants the Governor-in-Council the power to make regulations:

…

(b) declaring positions in railway companies to be critical to safe railway operations;

(c) respecting the following matters, in so far as they relate to safe railway operations, in relation to persons employed in positions referred to in paragraph (b):

(i) the training of those persons, both before and after appointment to those positions,

(ii) hours of work and rest periods to be observed by those persons,

(iii) minimum medical, including audiometric and optometric, standards to be met by those persons,

(iv) the control or prohibition of the consumption of alcoholic beverages and the use of drugs by those persons, and

(v) the establishment of support programs for those persons and standards applicable to such programs; and

(d) respecting the establishment of a scheme for licensing persons employed in positions referred to in paragraph (b), and prescribing the fees for the licences.

The Minister can order a railway company to establish rules relating to section 18 and the company must file the rules with the Minister. If no rules are forthcoming by the company or are not approved, the Minister may by order stipulate rules for that company.

A person who holds a position deemed critical to safe railway operations is required to undergo a medical examination (including hearing and vision) organized by the railway company concerned at intervals as determined in the regulations or rules.

In 1987, Transport Canada promulgated the *Railway Employee Qualification Standards Regulations*. These regulations set out the minimum qualifications required for engineers, transfer hostlers, conductors, and yard foremen. It is a process of certification and continuing competency assurance (every three years the person must be re-examined). The TSB wants more regulation in this area to tighten up the qualification process and require that training and qualification be conducted external to the railway companies.

Transport Canada approved Work/Rest Rules for Rail Operating Employees in 2003 pursuant to s 20(1) of the *Railway Safety Act*. These rules were developed through a consultative process involving railway companies, employees and their unions and some academics. It was developed as a rule, as rules are more flexible than regulations and can be amended more expediously when new evidence becomes available. The rules apply to operating employees and railways under the jurisdiction of the federal government. The principles underlying the rules are that:

1) to meet the safety and operational challenges of managing operating employee fatigue, railways, operating employees and their designated representatives must have a flexible approach that takes account of new developments in technology, meets employee's needs, meets the operational needs of the railway and can be implemented over a wide range of operating conditions.
2) railway companies have a responsibility to establish and maintain working conditions that allow employees to obtain adequate rest between tours of duty and alertness through the duty period. Employees also have a responsibility to report for work rested and fit for duty.[112]

The maximum continuous duty time for one tour of duty is 12 hours for freight trains in road service, 12 hours for passenger trains intercity or commuter, 16 hours for trains in work train service and 12 hours for yard service. The maximum is 18 hours in any 24 period (or 16 for yard service). If there is an emergency employees may stay on duty until relieved subject to fatigue management and reporting requirements. After going off duty at the home terminal after a ten hour or greater work tour, the employee must have eight hours off-duty, and for an away terminal, six hours.

All railways must, pursuant to the SMS regulations, implement fatigue management plans designed to reduce fatigue and improve on-duty awareness of operating employees. The plans must be developed in association with operating employees, or their designated representatives. The plans must consider employee work scheduling practices, education and training, on the job alertness strategies, rest environments, work environments, working under unusual working conditions, and deadheading (transportation of employees between locations). They must specifically address fatigue where employees work continuously for more than 12 hours or are on duty for more than 60 hours in a seven day period or emergency situations. The railway company must provide the plans, and any changes to them, to the Department. The railway company must file a report with the Department any time after an employee is on duty for greater than 12 hours in an emergency.

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[112] Transport Canada, "Work/Rest Rules for Rail Operating Employees 2003" (2003) at s. 2.

The Governor-in-Council may make regulations respecting the development and implementation of safety management systems (SMS) by railway companies, including the criteria to which the safety management systems must conform. The Act states: "If the Minister is of the opinion that the safety management system established by a railway company has deficiencies that risk compromising railway safety, the Minister may, by notice sent to the company, order the company to take the necessary corrective measures."[113]

A safety management system is a formal framework for integrating safety into day-to-day railway operations and includes safety goals and performance targets, risk assessment, responsibilities and authorities, rules and procedures and monitoring and evaluation processes. SMS systems are expected to improve railway safety by reducing: fatalities, property damage, and environmental impact. SMS are intended to promote a safety culture. Inspectors audit SMS programs through the use of a formalized auditing program and the analysis of safety performance indicators (in conjunction with the more traditional audits). However, one of the key issues with this program is that it was made assuming that the industry would act and therefore it lacks enforcement capabilities. Prosecution is too time consuming and expensive and safety is not enhanced by prosecuting, in fact it may be the opposite. There is also the difficulty of ensuring that SMS is embedded in the culture as opposed to being a paper tiger. The *Safety Management Systems Regulations* came into force on 31 March 2001. The regulations require that the components of the company's SMS system include at the minimum:

- safety policy
- Performance targets with associated initiatives to meet the targets signed off by a senior company official and communicated to employees
- clear authorities, responsibilities and accountabilities for safety at all levels of the railway company
- a system for involving employees and their representatives in the development and implementation of the SMS
- systems for identifying applicable railway safety regulations, rules, standards and orders and procedures for complying with them
- exemptions and procedures for demonstrating compliance with the terms and conditions of the exemption
- a process for identifying safety issues and concerns including those associated with human factors, third-parties and significant changes to railway operations
- evaluating and classifying risks by evaluating a risk assessment
- risk control strategies
- systems for accident and incident reporting, investigation, analysis and corrective action
- systems for ensuring that employees have appropriate skills and training and adequate supervision to ensure that they comply with safety requirements
- procedures for the collection of and analysis of data for assessing safety performance of the company

[113] *Railway Safety Act*, *supra* note 109 at s. 32(3.1).

- procedures for internal safety audits
- consolidated documentation for each component of the SMS.[114]

All of the above must be reported annually to the Minister.

Interface with the Public

Section 18(2) states that the Governor-in-Council may make regulations respecting crossing works, including regulations for requiring a railway company, road authority or other person who has rights relating to a road crossing to conduct a safety review of the road crossing following an accident of a type specified in the regulations.

Monitoring and Enforcement

The Minister has the power to appoint railway safety inspectors. Inspectors are certified for specific areas of responsibility: railway works, railway equipment, railway operations, or security matters. Railway safety inspectors monitor compliance with safety and security regulations, emergency directives, rules and orders made under the Railway Safety Act. Inspectors have the power to enter railway related sites, require the production of documents, seize property found in the course of inspection if the inspector believes that it is evidence of an offence under the Act and require the attendance of witnesses. Inspectors may forbid or restrict use of unsafe works or equipment, unsafe rail crossings, unsafe road crossing work, or the operation of certain works or equipment. A railway safety inspector is exempt from giving evidence in a civil case.

Inquiry Processes

Section 40 allows the Minister to order a public inquiry if he or she thinks there is an issue of public interest related to safe railway operations pursuant to regulations as long as it does not overlap with the work of the Transport Safety Board.

The Rail Safety Consultative Committee

The Rail Safety Consultative Committee is a permanent Ministerial committee comprised of Transport Canada employees and sector stakeholders. It was set up in 1999 but has been in recess for several years, as there are already plethoras of consultative mechanisms in place. The Rail Safety Consultative Committee:

- provides a forum for open communication between Transport Canada and their stakeholders on railway safety and environmental issues

[114] S.O.R./2001-37, s. 2.

- informs parties including railway companies, railway labour unions, other government bodies and representatives of the public
- establishes action priorities for the development of regulations and rules.[115]

The objectives of the RSCC are:

- to provide the Minister, the Department and the Transport Canada (T.C.) Rail Safety business line with stakeholder input to decisions on railway safety/environmental issues, including decisions with regard to the issuance of new regulations, revisions or revocations of existing regulations, and identification of alternatives to regulations for improving railway safety in Canada;
- to dialogue on railway safety issues and possible courses of action and to address those issues with a view to improving railway safety in Canada.[116]

The chair of the Committee establishes working groups to study and report on specific railway safety issues brought to the attention of the Committee. The working groups provide a report to the Committee which forwards the report to the Department for consideration. The Department may take no action, refer it back to the Committee for further direction, leave it to industry to manage, or take action. If the Department decides to institute new rules, the working group assists with the formulation of those rules.

Reporting

Transportation Safety Board Regulations determine what occurrences require either mandatory or voluntary reporting to the TSB. When a reportable accident or incident occurs, "the railway company, the track operator and any crew member aboard the rolling stock involved in the accident or incident shall report to the Board as much of the information" required as is both available and possible.[117]

Commercial Vehicles

The responsibility of ensuring road safety for the commercial vehicle sector in Canada is a complex one with authority split uneasily between the federal government and the provincial/territorial governments, with the bulk resting in provincial/territorial hands.

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[115] Rail Safety Consultative Committee, online: Transport Canada <http://www.tc.gc.ca/railway/RSCC/RSCC.htm>.
[116] Transport Canada, *Terms of Reference for the Rail Safety Consultative Committee* (Ottawa: Transport Canada, 1999), online: Transport Canada <http://www.tc.gc.ca/railway/RSCC/About/About.htm>.
[117] S.O.R./1992-446, s. 4.(1).

Product Safety

The Motor Vehicle Safety Act sets out safety framework at the federal level for vehicles. The legislation allows for safety related standards to be created, and inspections undertaken to determine compliance and safety. There is no after-market surveillance at the federal level although T.C. will act to recall products should they become aware of serious defects. Manufacturers are required to report defects in design, construction or functioning that may affect safety to the Minister as soon as they become aware of them.[118]

Operational Safety

Road safety was entirely a matter of provincial/territorial authority until 1954 when the Privy Council determined that the federal government had responsibility for commercial transport that operated across provincial lines.[119] The federal government immediately delegated this responsibility back to the provinces/territories as they had been addressing safety issues in the sector for a number of years. The *Motor Vehicle Transport Act, 1987* (*MVTA*) was the most recent Act to delegate day-to-day authority over inter-provincial commercial transport to the provinces/territories. Provinces continue to regulate commercial vehicles that do not cross provincial borders. The federal government retains the responsibility to promulgate regulations for the inter-provincial commercial vehicle transport industry and retains a facilitation role in respect of commercial vehicle regulation more generally.

The Canadian Council of Motor Transport Administrators (CCMTA) "is the official organization in Canada for coordinating all matters dealing with the administration, regulation and control of motor vehicle transportation and highway safety."[120] CCMTA incorporates members from all Canadian governments, as well as Associate members from transportation related organizations."[121] It is a consensus body that intends to reach agreement on how best to regulate safety. The CCMTA formulated a National Safety Code (NSC) for Motor Carriers from which to formulate provincial/territorial regulations to ensure consistent regulation of commercial vehicles.

The Code sets the following safety standards:

1. Makes it an offence to hold more than one license
2. Standardizes testing of commercial drivers and identifies what the government officials administering the tests evaluate

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[118] R.S.C. 1993, c. 6, s. 10.

[119] See *Winner*, *supra* note 25 where Winner's bus company was issued with a infringement ticket by a provincial inspector. His lawyer argued successfully before the Privy Council that the provincial enforcement officer had no authority to issue the ticket because Winner's company operated inter-provincially and therefore were within federal jurisdiction.

[120] Canada, House of Commons Standing Committee on Transport and Government Communications, *Commercial Vehicles Hours of Service - Interim Report* (Ottawa: Government of Canada, 2002) [*Commercial Vehicles Hours of Service*].

[121] Canadian Council of Motor Transport Administrators, online: <http://www.ccmta.ca/english/index.html> [Canadian Council of Motor Transport Administrators].

3. Sets standards for quality and training of driver examiners
4. Unifies licensing standards across provinces
5. Sets standards for training schools and permit carriers
6. Outlines the criteria for establishing driver fitness
7. Provides jurisdictions with access to records of driver and carrier performance
8. Sets criteria for short-term suspensions where a peace officer suspects impairment
9. Sets hours of service standards
10. Sets the standard for cargo securement
11. Sets maintenance and inspection standards
12. Outlines Commercial Vehicle Safety Alliance on-road inspection criteria
13. Sets daily trip inspection requirements
14. Establishes motor carrier safety rating standards
15. Outlines an audit process for the motor carrier safety rating standards
16. Sets standards for first aid training.[122]

However, provinces have interpreted these principles widely resulting in variances in the way in which commercial vehicles are regulated. However, there are two regulations that apply at a national level to determine aspects of operational safety outlined in the National Safety Code, namely hours of work and fitness certificate regulations.

The Motor Carrier Safety Fitness Regulations 2005

Each province/territory issues commercial vehicles with safety fitness certificates and has an audit process surrounding such certificates per the National Safety Code. However, there was considerable variance in these programs across provinces and territories. A consensus was reached that action needed to be taken to ensure a consistent framework across Canada to ensure safety and to ensure a level-playing field for all members of the industry. An amendment to the MTVA in 2001 requires all motor carriers (buses and trucks) to have a safety fitness certificate to operate on Canadian roads. The Regulations aim to provide a framework to enable provinces and territories to implement, consistently across Canada, a safety rating system for extra-provincial motor carriers. These Regulations would seek to ensure that "comparable motor carrier safety performance results in a similar safety rating regardless of jurisdiction so that safe motor carriers may compete on a level playing field across Canada, and eventually across North America."[123]

Under the Regulations, provinces and territories would monitor the safety performance of all extra-provincial motor carriers licenced in their jurisdiction by maintaining a complete

[122] The NSC is a considered a comprehensive code of minimum performance standards designed to ensure the safe operations of commercial vehicles, drivers and motor carriers. See Canadian Council of Motor Transport Administrators, "National Safety Code," online: Canadian Council of Motor Transport Administrators: <http://www.ccmta.ca/english/publicationandreports/publicationandreports.html#NSC>.
[123] Regulatory Impact Analysis Statement, *supra* note 70.

safety compliance profile of each motor carrier, using data input from all jurisdictions in which those carriers operate. All carriers initially would receive a Safety Fitness Certificate and be rated "Satisfactory – Unaudited", until such time as their safety performance and/or a facility audit resulted in a rating of "Satisfactory (Audited)", "Conditional" or "Unsatisfactory". A carrier rated "Unsatisfactory" would be prohibited from operating on Canadian roads.[124]

Commercial Vehicle Drivers Hours of Service Regulations, 1994

Fatigue in commercial road transportation is a major safety concern.[125] Organizations such as the U.S. Federal Motor Carrier Safety Administration suggest that "fatigue could be the cause in about 15 percent of annual road fatalities, while other sources suggest that the number could be considerably higher – up to 40 percent."[126] In response to concerns, T.C. consulted the scientific community and found that there is no single definitive solution to sleep and fatigue management in the transportation industry.[127] One reason that research on driver-fatigue remains inconclusive may be that sleep-experts conducting studies have to account for the differences between day and night driving, as well as the irregularity of work-schedules in the trucking sector.[128] Research would also have to take into account whether or not the data on work hours is reliable. The CCMTA notes that "data is sparse on the cause of accidents as a result of fatigue" and is mainly collected from police accident reports.[129] It is also assumed that fatigue is an underreported factor in accidents.[130] There is no good data from within Canada for two reasons: first, data is gathered from police forces across the country that record and report differently; second, fatigue may be a secondary or contributing factor to an incident that is simply not identified or reported.

Despite the degree of uncertainty as to the most optimal way in which to manage duty hours, government enacted regulations. These regulations stipulate the maximum number of hours a driver engaged in extra-provincial transportation can operate a commercial vehicle, and the minimum number of hours a driver must be off-duty before he or she returns to work. Drivers must keep records of their hours and produce the records at the request of an enforcement official. Federal and Provincial Hours of Service Regulations apply to the operators of motor carriers and commercial vehicles, as

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[124] *Ibid.*
[125] See *Commercial Vehicle Drivers Hours of Service Regulations: Regulatory Impact Analysis Statement*, C. Gaz. 2003.I., online: Canada Gazette: <http://canadagazette.gc.ca/partI/2003/20030215/html/regle1-e.html#i1> [*Commercial Vehicle Drivers*]; Gärtner, *supra* note 89 at 1025; Australia, Commonwealth, *Executive Summary: Report of Inquiry into Safety in the Long Haul Trucking Industry* by Michael Quinlan, online: Motor Accidents Authority < http://www.maa.nsw.gov.au/default.aspx?MenuID=189>.
[126] Canadian Council of Motor Transport Administrators, *supra* note 121.
[127] See *Commercial Vehicle Drivers*, *supra* note 125. See also *Commercial Vehicles Hours of Service*, *supra* note 120 at 6.
[128] *Commercial Vehicles Hours of Service*, *ibid.* at 5.
[129] Canadian Council of Motor Transport Administrators, *supra* note 121.
[130] *Ibid.*

defined by legislation. Although Federal Regulations apply to extra-provincial undertakings, the provinces enforce both Federal and Provincial Hours of Service Regulations.

Federal and Provincial regulations prohibit drivers from being on-duty for more than 15 hours, only 13 of which can be spent driving, and only after at least 8 consecutive hours have been spent off-duty.[131] The regulations also provide further detail on how on-duty and off-duty times are defined, and allow a driver to exceed on-duty times by no more than two hours when adverse conditions - such as poor weather - are encountered.[132]

Federal regulations outline three cycles or weekly caps that limit the amount of hours a driver can be on-duty during 7, 8, or 14 consecutive-day cycles. A driver can be on-duty for no more than 60 hours during a 7-day period; 70 hours during an 8-day period; 120 hours during a 14-day period.[133] If the 120 hour cycle is used, the driver must not "accumulate more than 75 hours of on-duty time without taking a minimum of 24 consecutive hours of off-duty time."[134]

Transport Canada monitors the implementation and enforcement of the *Commercial Vehicle Drivers Hours of Service Regulations* "through the meetings and discussions of the appropriate CCMTA standing committees, through bilateral discussions with jurisdictions and sector representatives, through periodic reporting and through occasional studies on implementation and consistency as may be undertaken by the Department."[135]

In 2002, the federal/provincial Council of Ministers responsible for Transportation and Highway Safety approved amendments to federal and provincial safety regulations in hopes of improving safety through reducing fatigue. The recommendations included the following:

1. 14 hours as the maximum per day for driving;
2. 14 hours as the maximum on-duty time;
3. two work-cycles (reduced from three) – 70 hours/7 days and 120 hours/14 days;
4. cycle switching[136] permitted only after minimum off-duty time of 36 hours in the 1st cycle or 72 hours in 2nd cycle;

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[131] *Commercial Vehicle Drivers Hours of Service Regulations, 1994*, S.O.R./94-716, ss. 7(1)(a)-(b) [*Hours of Service Regulations*].

[132] It should be noted that drivers' have expressed confusion over the definitions of "working day," "on-duty" and "off-duty," and that unless all parties involved in the sector understand and share these basic definitions, it is difficult to determine the effectiveness of current regulations as well as proposed recommendations. See Transport Canada, The Institute on Governance, *Ontario Motor Coach Passenger Safety Consultation: Report* (Ottawa: Government of Canada, 2000) [*Motor Coach Passenger Safety Consultation*].

[133] *Hours of Service Regulations*, *supra* note 131 at s. 7(2).

[134] *Ibid.* at s. 7(5).

[135] Canadian Council of Motor Transport Administrators, *supra* note 121.

[136] "Cycle-switching" allows a driver to move from one-cycle pattern to another and increase working hours beyond the maximum-levels stipulated on account of this legislative loop-hole. While the proposed amendments attempt to prevent (or at least curtail) this problem, some argue that the amendments do not go far enough, and even state that the proposals might even lead to increases in the amount of hours a driver

5. minimum 24 hour off-duty period every 14 days.[137]

Some groups have been critical of these proposed amendments and say they do not go far enough in improving safety. [138] The Communications, Energy and Paperworkers Union of Canada (CEP), representing around 1,000 truckers, stated in a brief that "the regulations proposed by Transport Canada and now under consideration by this Committee will do nothing to improve the situation and may make it worse." [139] Their particular critique is that the proposed rest-times do not provide "anything like sufficient time to recover from the long hours worked and would further undermine the family life of truck drivers."[140] Likewise, a spokesman for the Canadian Owner-Operators' Cooperative stated: "stress and fatigue are already major concerns under the present regulations, and warn that the incidence of accidents involving heavy vehicles is bound to increase proportionally with the increase of hours behind the wheel." [141]

Some concerned groups have recommended that Canada look to the U.S. standards as guidance for setting workload limits. The Bloc Québécois and NDP both favoured the U.S. standards where 10 hours/day is the maximum driving time and a 60 hour work week is enforced.[142] The Canadians for Responsible and Safe Highways (CRASH) expressed concern about the current disparity in the Canadian and U.S. limits and commented that the government must draw a line between business objectives and public safety when setting workload limits for truck and bus operators. [143] The Canadian Automobile Association recommended that harmonized standards in North America would "help to improve public understanding of fatigue issues related to commercial vehicle drivers."[144]

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spends "on-duty." See statements submitted by the Bloc and the NDP in *Commercial Vehicles Hours of Service*, *supra* note 120.

[137] *Ibid*.

[138] *Ibid.* at 15.

[139] *Ibid.* at 16.

[140] *Ibid.*

[141] *Ibid.*

[142] *Ibid.* at 20. Inconsistency between U.S. and Canadian regulation is a common concern. See *Motor Coach Passenger Safety Consultation*, *supra* note 132, where Transport Canada looks at drug and alcohol testing in the U.S. and considers whether or not drug testing should be introduced in Canada to extent that it has in the U.S. See Canadian Human Rights Commission, online: <http://www.chrc-ccdp.ca/default-en.asp?lang_update=1> for more on the law as it stands in Canada. See *Entrop v. Imperial Oil* (2000), 50 O.R. (3d) 18 (C.A.) where the Court distinguishes between alcohol tests (which can establish impairment at the time of testing) and drug tests (which establish prior use). In that case, the court determined that random drug testing for alcohol is permissible where employees hold "safety-sensitive positions." Whereas, drug testing does not meet the requirements of the *Meiorin* test that sets out the criteria for determining whether or not an employer has a bone fide occupational requirement to test an employee. However, "the Court held that drug testing for 'reasonable cause' or 'post-accident' and 'post-reinstatement', may be acceptable if 'necessary as one facet of a larger process of assessment of drug abuse.' Neither the tribunal nor the courts elaborated on what larger process of assessment is required."

[143] *Commercial Vehicles Hours of Service*, *supra* note 120 at 15.

[144] *Ibid.*

The *Commercial Vehicle Drivers Hours of Service Regulations 2005* come into force 1 January 2007.[145] The regulation is patterned on the National Safety Code Standard (NSCS), a comprehensive code of minimum performance standards designed to ensure the safe operations of commercial vehicles, drivers, and motor carriers.[146] Standard Nine of the NSCS contains basic rules on hours of service.

The Regulation's intent is to increase the opportunity to get more rest. Therefore, it sets out requirements for driving south or north of latitude 60°N. If driving south of latitude 60°N drivers may only drive for 13 hours per day and have 14 hours no-duty time. After this, drivers must take at least 8 consecutive hours off-duty and have ten hours off-duty time in a day (i.e. including breaks of no less than thirty minutes per day with one two hour block that is not included within the eight hour mandatory off-duty block of time), although two hours may be deferred as long as requirements are met. Drivers must also work in cycles of seven or 14 days with specified limits of total hours of on-duty time. If driving north of latitude 60°N the allowable working hours are longer (i.e. 15 driving and 18 of on-duty time). More flexibility was required for activities in the Yukon, the North West Territories and Nunavut (if a road is built) as winter ice roads, extensive road closures, a paucity of road pull offs and facilities and long stretches of isolated highway pose unique challenges.[147]

The Regulation contains exemptions for research or pilot project, although these require permits from federal directors. It also allows permits to be issued to vary these limits for commercial vehicles driving south of latitude 60°N and for oil well service vehicles. It also contains a limited exemption for drivers who are facing emergencies or adverse driving conditions.

The Regulation requires drivers to fill out a daily log book (paper or electronic) of on-duty and off-duty time, unless they work within a 160km radius of the home terminal or returns to his/her home terminal everyday or the motor carrier keeps the records. If a driver refuses to comply or falsifies the records, or mutilates or defaces the log a director or inspector may declare that driver out-of-service. The Provincial governments have the authority to enforce Hours of Service Regulations. While regulations require drivers to keep log-books, the log-book system does not guarantee that drivers are reporting hours accurately.[148] Members of the sector have acknowledged that doctoring and cheating practices occur.[149] For this reason, critics suggest that electronic methods of recording hours should replace the log-book system that dominates the sector.[150] The regulation also sets out the powers of inspectors to enforce these regulations.

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[145] *Commercial Vehicles Hours of Service Regulations 2005*, P.C. 2005-1816.
[146] Regulatory Impact Analysis Statement, C. Gaz. 2005. II. (*Commercial Vehicles Hours of Service Regulations*) [Regulatory Impact Analysis Statement – *Commercial Vehicles*].
[147] *Ibid.*
[148] See *Commercial Vehicles Hours of Service*, *supra* note 120 at 4, where it is stated that "there is a lack of scientific data to definitively establish the appropriate number of driving hours per day".
[149] *Motor Coach Passenger Safety Consultation*, *supra* note 132.
[150] But see *Commercial Vehicles Hours of Service*, *supra* note 120, where it is noted that critics argue that electronic on-board recorders should also be implemented in the U.S. and Mexico to be optimally effective.

The anticipated costs of these changes are expected to be minimal, but may include adjustments to logistics planning, shipping and receiving, training for inspectors and commercial vehicle drivers on the new regulations and adjustments to operating systems. However, the Regulatory Impact Analysis also notes that industry and governments have accepted these costs as a necessary outcome to improve safety.[151]

[151] Regulatory Impact Analysis Statement – *Commercial Vehicles*, *supra* note 146.

Patient Safety Law:
From Silos to Systems

Appendix 4:
KEY INFORMANTS

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Mary Thomson
Tom Ward
Fiona McDonald
Alison Shea

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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Patient Safety Law:
From Silos to Systems

Appendix 5:
DISSEMINATION

Jocelyn Downie
William Lahey
Don Ford
Elaine Gibson
Mary Thomson
Tom Ward
Fiona McDonald
Alison Shea

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

Completed Dissemination

Presentations

Fiona McDonald, "Patient Safety Law: From Silos to Systems" *Eastern Health* St. John's, Newfoundland - March 2006.

Fiona McDonald, "Patient Safety Law: From Silos to Systems" *Capital Health/Canadian Patient Safety Institute* Edmonton, Alberta – March 2006.

Fiona McDonald, "Patient Safety Law: From Silos to Systems" *Quality Council of Alberta* Calgary, Alberta – March 2006.

Fiona McDonald, "Patient Safety Law: From Silos to Systems" *Saskatchewan Health* Regina, Saskatchewan – March 2006.

Tom Ward & Fiona McDonald, "Patient Safety Law: From Silos to Systems" *Canadian Patient Safety Institute Board of Directors/Manitoba Patient Safety Institute (and invited guests)* Winnipeg, Manitoba – March 2006.

Fiona McDonald & Alison Shea, "Patient Safety Law: From Silos to Systems" *Nova Scotia Healthcare Safety Advisory Committee* Halifax, Nova Scotia - March 2006.

Fiona McDonald, "International Law Reforms Relating to Patient Safety: Lessons for Canada" *Canadian Bar Association (N.S.) Health Law Section* Halifax, Nova Scotia - February 2006.

Fiona McDonald, "International Legislative Responses to Patient Safety: A Comparative Assessment" *Patient Safety 2006*, Birmingham, U.K. – February 2006.

William Lahey & Fiona McDonald, "International Legislative Responses to Patient Safety: An Assessment" *Canadian Bioethics Society Conference*, Halifax, Nova Scotia – October 2005.

Poster Presentation

Fiona McDonald *et al*. "International Legislative Responses to Patient Safety: An Assessment" *Halifax Five: The Canadian Healthcare Safety Symposium* Calgary, Alberta – October 2005.

Meetings

Meeting with the Health Quality Council of Saskatchewan, March 2006 (Laurie Gander).

National Consultation Meeting, Halifax, Nova Scotia, February 2006.

Small Group Meeting, “Occupational Safety and Health” Halifax, Nova Scotia, December 2005.

Small Group Meeting, “Evidentiary Protections” Halifax, Nova Scotia, December 2005.

Small Group Meeting, “Institutional Regulation” Halifax, Nova Scotia, November 2005.

Small Group Meeting, “No Fault/Medical Malpractice” Halifax, Nova Scotia, November 2005.

Small Group Meeting, “Professional Regulation” Halifax, Nova Scotia, November 2005.

Web-Site Postings

Report and appendices posted on Dalhousie Health Law Institute website at: <http://hli.law.dal.ca/>.

Power-point presentation - Fiona McDonald, “International Legislative Responses to Patient Safety: A Comparative Assessment” *Patient Safety 2006*, Birmingham, U.K. – February 2006, online: saferhealthcare (Innovations and Research Presentations) <http://www.saferhealthcare.org.uk/IHI/ProgrammesAndEvents/ConferencesAndTraining/Patient+Safety2006.htm>.

Other

Reports sent to the following:

- All Ministers of Health in Canada
- All Deputy Ministers of Health in Canada
- All Departments of Justice in Canada
- Canadian Patient Safety Institute
- Manitoba Patient Safety Institute
- The Quality Council of Alberta
- Health Quality Council of Saskatchewan
- Ontario Hospital Association
- Key informants
- Canadian Medical Association
- Canadian Nurses Association

Planned Additional Dissemination

Conferences

We plan to submit abstracts to a variety of conferences including:

- IAMRA *7th Annual Conference on Medical Regulation* Wellington, New Zealand, November 2006.
- Canadian Association for Health Services and Policy Research Conference *Insight, Interaction and Innovation: New Approaches to Health Services, Research, Policy and Management* Vancouver, British Columbia, September 2006
- Canadian Centre for Elder Law Studies, *Canadian Conference on Elder Law Studies* Vancouver British Columbia, October/November 2006.

Papers

We plan to write a number of articles including:

- Patient Safety Law: From Silos to Systems
- Danish Patient Safety Systems
- Working to Death: Work Hours, Patient Safety and Governance
- Thinking Safety in the Regulation of Long-term Care

Web-linkages

We will advise the following additional groups of our report so they can provide links if they choose:

- Open Clinical
- Ontario Hospital Association Patient Safety Support Network
- University of Manitoba Patient Safety List-serve
- Canadian Patient Safety Institute