

**CANADA**

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## Canada

Canada is a federalist constitutional monarchy. The population of Canada is estimated at 32,500,000 people<sup>1</sup> with 90 percent of that population within 160 km of the border with the United States.

## Health Care System Context

### Law

Canada has two legal systems. Federally and in all of the provinces and territories, except Québec, the legal system is based upon the common law system. In Québec, a civil law system based on French law is in place.

### Health

The central pillar of the Canadian health system is the single payer principle that the cost of health care should be paid through the tax system. The health system has become a source of pride and is thought to define what it means to be Canadian.<sup>2</sup> However, it is important to note that the majority of health services in Canada are not government services delivered by government employees or institutions, but rather are privately provided by independent institutions or individual independent health professionals.

Canada's health system is noted by some commentators to give predominant weight in the formation of policy and the operation of the health system to the medical profession and it uses collegial mechanisms of governance.<sup>3</sup>

### *Federal, Provincial and Territorial Responsibilities*

In Canada, the responsibility for the health system is divided between the federal and provincial/territorial governments pursuant to the *Constitution Act 1867*.<sup>4</sup> As Hogg states:

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<sup>1</sup> Statistics Canada, online: Statistics Canada <<http://www.statcan.ca/english/edu/clock/population.htm>>.

<sup>2</sup> William Lahey, "The Legal Framework of Canada's Health Care System" in Jocelyn Downie, Karen McEwen and William MacInnis, *Dental Law in Canada* (Markham, Ont.: Butterworths, 2004) 29 at 51.

<sup>3</sup> 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).

<sup>4</sup> *Constitution Act, 1867* (U.K.), 30 & 31 Vict., c. 3, reprinted in R.S.C. 1985, App. II, No. 5.

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.<sup>5</sup>

Despite this, health is traditionally considered as primarily resting within the sphere of provincial and territorial power and authority. The *Constitution Act* gives the provinces the authority to make and administer laws for the “establishment, maintenance and management of hospitals ...”.<sup>6</sup> It also gives the provinces the power to make laws and “property and civil rights” (interpreted by the courts to mean professional services) and public insurance against social and economic hardship.

The federal government’s role is set out in the *Constitution Act*. The federal government can use its spending powers in relation to the health system. It has established a subsidy system for health insurance schemes and funds health system research. The federal government also has a role in relation to the regulation of certain activities (e.g. pharmaceutical research) and products (e.g. drugs and devices). In relation to services, the federal government funds and provides services to First Nations and Inuit peoples. Since the mid-1980s the federal government has passed much of the responsibility for planning and provision of health services to local First Nations and Inuit communities.

The responsibilities of the federal Minister of Health are set out in the *Department of Health Act*.<sup>7</sup> These include:

- (a) the administration of such Acts of Parliament and of orders or regulations of the Government of Canada as are not by law assigned to any other department of the Government of Canada or any minister of that Government relating in any way to the health of the people of Canada;
- (a.1) the promotion and preservation of the physical, mental and social well-being of the people of Canada;
- (b) the protection of the people of Canada against risks to health and the spreading of diseases;
- (c) investigation and research into public health, including the monitoring of diseases;
- (d) the establishment and control of safety standards and safety information requirements for consumer products and of safety information requirements for products intended for use in the workplace;
- (e) the protection of public health on railways, ships, aircraft and all other methods of transportation, and their ancillary services;

<sup>5</sup> P. Hogg, *Constitutional Law of Canada*, 4<sup>th</sup> ed. (Scarborough, Ont.: Carswell Publishing, 1997) at 445.

<sup>6</sup> *Constitution Act*, *supra* note 4. See also discussion in C. Flood, “The Structure and Dynamics of Canada’s Health Care System” in Jocelyn Downie, Timothy Caulfield & Colleen M. Flood, eds., *Canadian Health Law and Policy* (Markham, Ont.: Butterworths, 1999) at 5; M. Jackman “Constitutional Jurisdiction over Health in Canada” (2000) 8 Health L. J.; Canada, Commission of the Future of Health Care in Canada, *Constitutional Jurisdiction Over Health and HealthCare Services in Canada* (Discussion Paper No. 12) by H. Leeson (Ottawa: Commission on the Future of Health Care in Canada, 2002).

<sup>7</sup> *Department of Health Act*, S.C. 1996, c. 8.

- (f) the promotion and preservation of the health of the public servants and other employees of the Government of Canada;
- (g) the enforcement of any rules or regulations made by the International Joint Commission, promulgated pursuant to the treaty between the United States of America and His Majesty, King Edward VII, relating to boundary waters and questions arising between the United States and Canada, in so far as they relate to public health;
- (h) subject to the *Statistics Act*, the collection, analysis, interpretation, publication and distribution of information relating to public health; and
- (i) cooperation with provincial authorities with a view to the coordination of efforts made or proposed for preserving and improving public health.<sup>8</sup>

The federal government's responsibilities, and more specifically the responsibilities of the Minister, are functionally carried out by a variety of agencies. Chief among them is Health Canada. Health Canada administers the *Canada Health Act*, funds the Canada Health Transfer and First Nations and Inuit organizations and communities and other organizations, regulates products, environmental health and protection, provides and funds health services for Inuit and First Nations communities and funds and conducts research. Health Canada reports to and is under the direction of the federal Minister of Health. Health Canada administers a number of federal Acts that have a bearing on the safety of the health system such as the *Food and Drugs Act*, *The Controlled Drugs and Substances Act*, *The Hazardous Products Act*, *The Canadian Environmental Protection Act*, *The Radiation Emitting Devices Act*, *the Tobacco Act*, and the *Assisted Human Reproduction Act*.

Responsibility for public health is jointly shared between the federal government and the provinces/territories. In 2004 the federal government, with the agreement of the provinces/territories, set up the Public Health Agency of Canada. This Agency too reports to and is directed by the federal Minister of Health. Its role is to take actions to prevent chronic diseases, like cancer and heart disease, prevent injuries and respond to public health emergencies and infectious disease outbreaks. It administers the *Quarantine Act 1985* and the newly enacted, but not yet in force, *Quarantine Act 2005*.

The federal government also funds the Canadian Institutes of Health Research, the Canadian Patient Safety Institute, the Canadian Health Services Research Foundation and other research related agencies which are independent of government. It also, in conjunction with the provinces/territories, funds the Canadian Institute for Health Information, which generates and provides health information, again independent of government.

Provinces and territories have a broad role in relation to the regulation of health systems in Canada. Provincial/territorial governments are responsible for:

- Managing the system (through the develop of legislation, regulation and standards)
- regulating the quality and safety of health services, whether or not they fund them

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<sup>8</sup> *Ibid* at s. 4(2).

- administering provincial programs such as public health services or health research programs
- funding health services

All provinces and territories have a Minister responsible for health and a Department also responsible for health and sometimes social services. Departments are responsible for providing general policy and planning advice to the Minister and for setting the framework to regulate hospitals and other health facilities or services and personnel and for enforcing this framework. They also provide or administer provincial health programs, such as public health services. Some provinces also fund health related research.

All provinces in Canada have moved towards the regionalization of health systems. Governance and management responsibilities for, at the minimum, hospitals but sometimes also long-term care facilities and home care, have been transferred by statute from individual hospitals to newly created regional authorities. In addition, in some provinces some policy and planning responsibilities have also been devolved from the centralized Departments of Health.

As will be explained in greater detail in the next section, responsibility for funding Medicare is shared between provincial and federal governments. All provinces/territories are required to have an independent publicly administered agency to administer their Medicare programs. Provinces also fund services that are supplementary to the federally supported Medicare plan, such as home care, prescriptions, long-term care and dental care. However, coverage of additional services varies from province to province/territory depending on provincial fiscal capacities. Often additional services are means tested, require co-payment and subject to deductibles.

### ***Medicare***

In 1947 the province of Saskatchewan established a universal hospital insurance program, an initiative subsequently adopted by several other provinces. In 1957 the federal government offered a 50/50 federal cost-sharing plan to any province that adopted a similar hospital insurance program, an offer all had accepted by 1961. In 1960 the Hall Commission was asked by the federal government to study health care reform. The Hall report in 1964 recommended the national adoption of the Saskatchewan model, which had in the meantime expanded to include physician services. The rationales behind the recommendation were social justice and sound financial management. In 1966, the Federal government established a federal subsidy scheme for provincial and territorial health insurance plans to provide free and universal coverage for physician and hospital services (Medicare). From 1977, the contribution by the federal government was systematically reduced in the name of fiscal retrenchment until the *2003 First Ministers*

*Accord on Health Care Renewal*<sup>9</sup> saw a significant reinvestment by the federal government.

Currently, to obtain federal funding each insurance plan must comply with five principles set out in the *Canada Health Act 1984*,<sup>10</sup> so there is some degree of uniformity, albeit significant differences in service coverage and systemic design remain. The five principles are public administration, universality, portability, comprehensiveness and accessibility. The *Canada Health Act* demands non-profit administration of health insurance, universality of treatment within each province, and portability between provinces.<sup>11</sup> Comprehensive coverage is required for “medically necessary” services, although this term is undefined resulting in some variation in coverage between provinces. Accessibility creates a general requirement of accessibility and deals with issues relating to physician compensation and the funding of hospitals and user charges and extra billing.<sup>12</sup> This provision “set[s] Canada’s health care system apart from all the others. No other system goes so far in making the state the exclusive source of financing for medical services.”<sup>13</sup> This exclusivity may be under threat with the Supreme Court of Canada recently stating in the *Chaoulli*<sup>14</sup> case that the Québec government had failed to provide reasonable access within the publicly funded system and had violated patients’ rights by prohibiting them from obtaining necessary care through private insurance.

### ***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.<sup>15</sup> Each country studied had different areas of good performance and weakness. In Canada, cancer survival rates were generally average or above average and were highest for childhood leukemia. It also had high transplant survival rates. Canadians reported very few financial barriers to getting medical care, diagnostic tests, or prescription drugs. However, acute myocardial infarction (heart attack) case-fatality was higher in Canada than in Australia or New Zealand in older age groups. Pertussis incidence was much higher than some of the other countries studied. Canadians reported difficulty seeing a specialist, getting care on nights and weekends, and getting same-day doctor appointments when needed.

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<sup>9</sup> Health Canada, *2003 First Minister’s Accord on Health Care Renewal*, online: Health Canada <[http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2003accord/index\\_e.html](http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2003accord/index_e.html)>.

<sup>10</sup> *Canada Health Act*, R.S.C. 1985, c. C-6.

<sup>11</sup> Lahey, *supra* note 2 at 61-62.

<sup>12</sup> *Ibid* at 69.

<sup>13</sup> *Ibid* at 71.

<sup>14</sup> *Chaoulli v Quebec (Attorney-General)*, [2005] 791 S.C.R. 35.

<sup>15</sup> 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.cmf.org>>.

The World Health Organization examined the relative performance of health systems of member countries.<sup>16</sup> 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 Canada ranked 7 on that list (the United Kingdom 9, Australia 12, New Zealand 26, U.S. 15, and Denmark 20).<sup>17</sup> The study also examined how efficiently health systems translate expenditure into health in regard to the overall achievement to expenditure. Canada ranked number 30 in the world (the United Kingdom 18, New Zealand 41, Australia 32, Denmark 34, and the U.S. 37).<sup>18</sup> 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). Canada ranked 7-8 in the world (U.K. ranked 26-27 (with Qatar) the U.S. 1, Denmark 4, New Zealand 22-23, Australia 12-13). In terms of distribution of responsiveness (disadvantaged groups) Canada ranked 3-38 (i.e. third equal with 37 other countries, including the U.S., the U.K., New Zealand, Denmark and Australia).

In 2000 Canada's per capita health spending was relatively high at \$2,535. In contrast New Zealand spent \$1,623; \$1,763 was spent in the United Kingdom, \$2,211 in Australia, and \$4,631 in the United States.<sup>19</sup>

## Patient Safety

### Key Statistics

Recent empirical work has suggested that Canadian hospitals have an unsafe event rate of 7.5 percent of which 37 percent are preventable with a death rate of 0.66 percent.<sup>20</sup>

### Patient Safety Initiatives

In 2001 the National Steering Committee on Patient Safety was established. In 2002 it published a report *Building a Safer System*.<sup>21</sup> In this report it proposed a national

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<sup>16</sup> The World Health Organization, *The World Health Report 2000* (Geneva: The World Health Organization, 2004).

<sup>17</sup> Because of statistical uncertainty Canada, the U.K. and Australia are in the same range with less than 0.5 percent difference between them.

<sup>18</sup> Canada, Australia and Denmark are in the same range.

<sup>19</sup> 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.

<sup>20</sup> G. Baker *et al.*, "The Canadian Adverse Events Study: The Incidence of Adverse Events Among Hospital Patients in Canada" (2004) 170 C.M.A.J. 1678.

integrated strategy for improving patient safety in Canadian healthcare. One of its key recommendations was the establishment of a Canadian Patient Safety Institute (CPSI), intended to promote innovative solutions and to facilitate collaboration among governments and stakeholders to enhance patient safety. The Health Accord between the federal and provincial governments in 2003 committed to implementing the recommendations of the National Steering Committee and to the establishment of the Canadian Patient Safety Institute. As part of the Accord, the Federal government of Canada committed \$50 million to patient safety (\$10 million for five years).

Health Canada created and announced the funding for the Canadian Patient Safety Institute in late 2003. The Institute became operational in 2004 as an independent not-for-profit corporation. It is not a regulatory agency rather it sees its role as:

- fostering a system where knowledge and information about optimal patient safety practices are shared;
- influencing the necessary cultural shifts and championing changes in systems to improve patient safety;
- collaborating with stakeholders in an ongoing dialogue to support improvements in patient safety.<sup>22</sup>

It also funds research into patient safety.

In addition, there are some provincial initiatives to support patient safety (only one of these is a regulatory agency). These include:

- the British Columbia Patient Safety Taskforce, a provincial coalition supported by the Ministry of Health Services;<sup>23</sup>
- the Health Quality Council of Alberta, an agency created and funded by the Minister of Health and Wellness. Its role is to report, survey, identify concerns about health system quality, analyze trends, collaborate with health regions and stakeholders such as the Canadian Patient Safety Institute to define best practices and facilitate knowledge transfer of leading health care practices throughout Alberta, and to advise the Minister of Health and Wellness on the quality of Alberta's health system and areas for quality research;<sup>24</sup>
- the Health Quality Council of Saskatchewan (discussed in more detail in the section entitled “Other Legislative Instruments”);
- the Manitoba Institute for Patient Safety, an independent non-profit organization created and funded by the Manitoba government in 2004 pursuant to the recommendations made by the Manitoba Patient Safety Steering Committee. The Institute will promote, coordinate and facilitate activities that have a positive

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<sup>21</sup> National Steering Committee on Patient Safety, *Building a Safer System: A National Integrated Strategy for Improving Patient Safety in Canadian Health Care* (2002) online: RCPSC <[http://rcpsc.medical.org/publications/building\\_a\\_safer\\_system\\_e.pdf](http://rcpsc.medical.org/publications/building_a_safer_system_e.pdf)> [National Steering Committee].

<sup>22</sup> Canadian Patient Safety Agency, online: CPSI <<http://www.patientsafetyinstitute.ca>>.

<sup>23</sup> B.C. Ministry of Health Services, News Release/Communiqué, “Provincial taskforce to Improve Patient Safety” (7 May 2004) online Government B.C. <[http://www2.news.gov.bc.ca/nrm\\_news\\_releases/2004HSER0018-000280.pdf](http://www2.news.gov.bc.ca/nrm_news_releases/2004HSER0018-000280.pdf)>

<sup>24</sup> Alberta Health Quality Council, online: HQCA <<http://www.hqca.ca/index.html>>.

- impact on patient safety throughout Manitoba while enhancing the quality of health care for Manitobans;<sup>25</sup>
- Ontario Hospital Association Patient Safety Support Service funded by the Ministry of Health and Long-term Care for two years to provide information, tools, and training to promote effective strategies that enhance patient safety;<sup>26</sup>
  - Healthcare Safety Advisory Committee in Nova Scotia.<sup>27</sup>

## Institutional Regulation

### Introduction

An important aspect of the Canadian health system is the institutions within which some health services are provided. These institutions include: hospitals, long-term care facilities, other residential and non-residential facilities, and private healthcare facilities. Under the *Constitution Act 1867*<sup>28</sup> provinces have the responsibility for the “Establishment, Maintenance and Management of Hospitals”. Provinces are also responsible for other types of health facilities, such as long-term care facilities. Within “maintenance and management” is included responsibility for regulating the quality, and thus safety, of health services, whether these services are funded by government or not.<sup>29</sup> However, it is important to note that safety and quality are regulated by all players in the sector, to a greater or lesser extent, with the facilities themselves playing a crucial role in the fostering of patient safety. Patients also play a role through the use of tort law.

Traditionally, government regulation of health care has been dominated by the philosophy that patient safety and healthcare quality are best managed by those with expertise, most often physicians but also healthcare facilities. Thus government primarily has seen its role as to “regulate and guide action in a relatively consistent way, providing minimum standards of conduct and relief from harm.”<sup>30</sup> Minimum standards are provided through the use of statute and regulation and agency oversight.

### Hospitals

A primary method of regulating healthcare facilities is through a licensing process. Most provinces do not require that public hospitals be licensed. Some provinces, such as

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<sup>25</sup> Manitoba Institute for Patient Safety, online: MBIPS <<http://www.mbips.ca/aboutus.html>>.

<sup>26</sup> Patient Safety Support Service, online: Ontario Hospital Association <[http://www.oha.com/client/oha\\_lp4w\\_ind\\_webstation.nsf/page/Patient+Safety+Support+Service](http://www.oha.com/client/oha_lp4w_ind_webstation.nsf/page/Patient+Safety+Support+Service)>.

<sup>27</sup> Health Care Safety Working Group, online: Department of Health Nova Scotia <[http://www.gov.ns.ca/health/health\\_care\\_safety/provincial.htm](http://www.gov.ns.ca/health/health_care_safety/provincial.htm)>.

<sup>28</sup> *Constitution Act*, *supra* note 4.

<sup>29</sup> Lahey, *supra* note 2 at 39.

<sup>30</sup> P. Hirst, & G. Thompson, “Globalization and the Future of the Nation State” (1995) 24 *Economy & Society* 408.

British Columbia, require the licensing of private hospitals but many provinces do not.<sup>31</sup> Licensing is usually a limited process. In British Columbia again for example, applicants must provide their name address and occupation, a statement of their interest in the facility, the maximum number of patients the facility will accommodate, a legal description of the land, description of the premises, photo of the facility, floor plan, dimensions of rooms, statement of sanitary arrangements, description of fire escapes and statement about the classes of patients to be admitted. A license can be granted if the chief inspector approves the building and the character and fitness of the applicant is established (s. 7). Licenses are usually granted for one year and can be revoked for cause.<sup>32</sup>

Another primary method is monitoring to ensure basic minimum standards. Monitoring is a function of government in all provinces across Canada. In Alberta, section 7 of the *Health Facilities Review Committee Act*<sup>33</sup> requires the Alberta Health Facilities Review Committee to visit all facilities which operate under the *Hospitals Act*, the *Nursing Homes Act* or the *Regional Health Authorities Act* (all approved acute care and auxiliary care hospitals, nursing homes, mental health hospitals and special care centres) for “the purpose of reviewing and inspecting them and the manner in which they are operated.” In practice, after each visit a written report is sent to the chair of the regional health authority, the chief executive officer of the regional health authority, the administrator of the facility, and the Minister of Health and Wellness. If the facility is privately owned or operated, the Committee sends a joint letter to the regional health authority and the owner or senior representative of the non-profit or private organization which operates the facility. If a major concern is identified at a facility, the Committee will bring it to the attention of the Minister of Health and Wellness. The Committee is required by law to prepare an annual report which is tabled in the Legislative Assembly of Alberta.<sup>34</sup>

In British Columbia, the *Hospital Act*<sup>35</sup> contains provision for inspections of hospitals and private hospitals, as does the New Brunswick *General Regulation - Hospital Act*<sup>36</sup> and the *Hospital Management Regulations*<sup>37</sup> from Prince Edward Island. In Manitoba, section 23(2)(k) of the *Regional Health Authorities Act*<sup>38</sup> states that the Regional Health Authority shall: “monitor and evaluate the delivery of health services and compliance with prescribed standards and provincial objectives and priorities, in accordance with guidelines provided or prescribed by the minister.” Section 9 of the Manitoba *Private*

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<sup>31</sup> Private hospitals generally, although not exclusively, provide health services that are not covered by Medicare, for example, cosmetic surgery. Some provinces use law to regulate the facilities, for example, B.C., Manitoba and Ontario all regulate private hospitals or independent health care facilities, whereas Alberta regulates types of services i.e. surgical facilities, public or private.

<sup>32</sup> *Hospital Act*, R.S.B.C. 1996, c. 200.

<sup>33</sup> R.S.A. 2000, c. H-3.

<sup>34</sup> Alberta Health Facilities Review Board, online: Alberta Health and Wellness <<http://www.health.gov.ab.ca/about/HFRC/index.html>>.

<sup>35</sup> *Supra* note 32.

<sup>36</sup> N.B. Reg. 1992-84, s. 49.

<sup>37</sup> P.E.I. Reg. EC1976-574, s.10.

<sup>38</sup> C.C.S.M, c. R34.

*Hospitals Regulations*<sup>39</sup> (58/93) authorizes inspectors to make regular inspections of all private hospitals, as does section 10 of the *Hospitals Act*.<sup>40</sup>

Few provinces require facilities to be accredited. In Quebec, the *Act Respecting Health Services and Social Services* states that every institution must have the health and social services it provides accredited by a recognized accreditation body.<sup>41</sup> A condensed summary must be sent to the Minister, the regional board and relevant professional orders. In Alberta the position is less definitive with the *Operation of Approved Hospitals Regulation* stating that “each hospital shall strive to meet the standards for accreditation of hospitals established by the Canadian Council on Hospital Accreditation.”<sup>42</sup> The renamed Canadian Council on Health Services Accreditation has “Patient Safety Goals and Required Organizational Practices” as well as a range of other accreditation standards that must be met in order to achieve accreditation. In Alberta, the *Health Care Protection Act*<sup>43</sup> states that surgical facilities, whether providing insured services or not, must be accredited by the College of Physicians and Surgeons of Alberta or the Dental Facilities Accreditation Committee (s. 7, 13, & 16).

Few provinces have clear accountability structures around safety or quality within the health system in that province. In Québec, the *Act Respecting Health Services and Social Services*<sup>44</sup> requires each public institution to enter into a management and accountability agreement with the regional board, which must set out the mission and strategic directions of the institution, an annual action plan describing the objectives for the first year of the agreement, measures to be taken to achieve them and main indicators to be used in measuring the results. The Act also requires the creation of a risk and quality management committee in each institution. The functions of this committee include seeking, developing and promoting ways to:

- 1) identify and analyze incident or accident risks to ensure the safety of users;
- 2) make sure support is provided to the victim and relatives of the victim; and
- 3) establish a monitoring system including the creation of a local register of incidents and accidents for the purpose of analyzing the causes of incidents and accidents, and recommend to the board of directors of the institution measures to prevent such incidents and accidents from reoccurring and any control measures.

The Minister is also required under this Act to take measures to “ensure users the safe provision of health services and social services”.<sup>45</sup>

In Manitoba, section 3(2) of the *Health Services Insurance Act*<sup>46</sup> states that the Minister has the power “to ensure that adequate standards are maintained in hospitals, personal

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<sup>39</sup> Man. Reg. 58/1993.

<sup>40</sup> C.C.S.M. c. H120.

<sup>41</sup> R.S.Q., chap. S-4.2, Div. II.I, s. 107.1 [*Health Services and Social Services Act*].

<sup>42</sup> Alta. Reg. 247/1990.

<sup>43</sup> R.S.A. 2000, c. H-1.

<sup>44</sup> *Health Services and Social Services Act*, *supra* note 41 at s. 182.2.

<sup>45</sup> *Ibid.* at s. 183.2

<sup>46</sup> C.C.S.M. c. H35.

care homes and related health facilities, including standards respecting supervision, licensing, equipment and inspection, or to make such arrangements as the Minister considers necessary to ensure that adequate standards are maintained.” Section 23(2)(g)(ii) of the *Regional Health Authorities Act*<sup>47</sup> states that the Regional Health Authority shall: “in providing for the delivery of health services, ... comply with, and ensure compliance with, prescribed standards.”

Laws in some provinces create bodies within hospitals to address patient safety and quality related issues. In Manitoba, the *Hospitals Standards Regulation*<sup>48</sup> sets out the responsibilities of Hospital Standards Committees (established in section 24 of the *Hospitals Act*) to ensure that a medical audit program is undertaken to provide surveillance of quality of care. In the Northwest Territories, the *Hospital Standards Regulations* creates a health services committee in each institution to examine, discuss and make recommendations to the hospital authority and, where necessary, the Minister with respect to, amongst other things “improving diagnostic and treatment standards within the hospital or hospitals”.<sup>49</sup>

Another body commonly used to ensure quality and safety in hospitals in all provinces is self-regulatory in nature. The medical profession is delegated authority to award staff privileges to physicians to practice within that facility. The medical staff and the Board create by-laws setting out the relationship between the facility and its medical staff. By-laws “may be regarded as internal quasi-legislative rules governing the organization, management and operation of the institution.”<sup>50</sup> These by-laws also govern the standards to be expected of physicians to operate within the facility. The process of awarding privileges is through the careful selection of physicians who are qualified and competent and through continuing oversight of their practice.

Structural issues are also regulated, to a lesser extent than in the Long-term Care/Residential Care sectors, but there is variance between provinces. Working hours in Canadian Hospitals are determined through negotiations by unionized employees or through accreditation processes for medical education. In Prince Edward Island, the *Hospital Management Regulations*<sup>51</sup> set out staff/patient ratios for the employment of registered nurses in hospitals. Manitoba’s *Private Hospitals Regulations*<sup>52</sup> set out minimal staffing requirements for private hospitals.

Lastly, government can use a standard setting function as a tool to improve patient safety. Legislation/regulations in most provinces contain basic standards pertaining to such things as record keeping, the admission of patients, rules relating to surgery, tissue disposal, restraints, and other aspects of care, treatment or patients rights. Often there is provision for government to make regulations in respect of certain issues but it may not

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<sup>47</sup> *Supra* note 38.

<sup>48</sup> Man. Reg. 453/88R.

<sup>49</sup> N.W.T. Reg. 1990, c. T-6, s. 61(5)(a)(iii).

<sup>50</sup> B. Marshall & D. Kelly, eds., *Canadian Health Facilities Law Guide* (North York, Ont.: CCH Canadian Ltd., 1997) at 514.

<sup>51</sup> *Supra* note 37 at s. 16.

<sup>52</sup> *Supra* note 39.

be used. In British Columbia, the *Health Authorities Act*<sup>53</sup> states that the Minister may by regulation establish provincial standards for health services (s. 3). Similarly, in Manitoba, in section 3(2) of the *Regional Health Authorities Act*<sup>54</sup> the Minister may prescribe standards for the provision of health services. In Alberta, the *Hospitals Act*<sup>55</sup> states that regulations may be made prescribing the standards of service to be provided by approved hospitals. In Manitoba, the *Hospitals Act* allows regulations to be made in respect of methods of treatment and minimum equipment standards.<sup>56</sup> In British Columbia, regulations may be made in respect of “the rules or standards regarding the care and treatment of patients”.<sup>57</sup> In Newfoundland, the *Hospitals Act*<sup>58</sup> also enables the making of regulations in respect of safety.

### Long-Term Care and Other Residential Care Facilities

A primary method of regulation in this sector is through licensing and monitoring. In Prince Edward Island the *Community Care Facilities and Nursing Homes Act*<sup>59</sup> creates a Board that is tasked with licensing facilities, advising on standards and the care and service provided in them, monitor the operation of facilities or nursing services.

Section 12(1) of the Alberta *Nursing Homes Act*<sup>60</sup> authorizes inspection of premises or requires the provision of information to ensure “the health, safety or well-being of the residents” and compliance with the Act and its regulations. Violation can result in an order for the facility to create a correction plan, cancellation of the funding contract, order no new residents be admitted or the appointment of an administrator. Section 7 of the British Columbia *Continuing Care Act*<sup>61</sup> permits inspectors to inspect records and the facility as does section 118.4 of the Manitoban *Health Services Insurance Act*.<sup>62</sup> Section 25 of the *Nursing Homes Act*<sup>63</sup> from New Brunswick also authorises inspections. The *General Regulations – Nursing Homes* state that inspectors must visually examine one or more residents of the home to assess their overall health and well-being.<sup>64</sup> Section 10 of the New Brunswick *Nursing Homes Act* also requires the completion of accident/incident reports by staff.<sup>65</sup> In Nova Scotia the *Homes for Special Care Act*<sup>66</sup> also authorises inspections. The *Homes for Special Care Regulations* amplify these requirements by making it clear that nursing homes and nursing sections in homes for special care must be inspected at least twice a year and residential care facilities, homes for the aged and

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<sup>53</sup> R.S.B.C. 1996, c. 180.

<sup>54</sup> *Supra* note 38.

<sup>55</sup> R.S.A. 2000, c.H-12, s.28(b).

<sup>56</sup> *Supra* note 40.

<sup>57</sup> *Supra* note 32 at s. 56(g).

<sup>58</sup> R.S.N.L. 1990 c. H-9 s.37(a).

<sup>59</sup> R.S.P.E.I. 1988, c. C-13, s. 6.

<sup>60</sup> R.S.A. 2000, c. N-7.

<sup>61</sup> R.S.B.C. 1996, c. 70.

<sup>62</sup> *Supra* note 46.

<sup>63</sup> S.N.B. 1982, c.N-11.

<sup>64</sup> N.B. Reg. 1985-187, s. 40(1).

<sup>65</sup> *Supra* note 63.

<sup>66</sup> R.S.N.S. 1989, c. 203, s. 10.

homes for the disabled once a year.<sup>67</sup> In Prince Edward Island inspectors, under the authority of the *Community Care Facilities and Nursing Homes Act*, must conduct periodic inspections and report his/her findings to the Board.<sup>68</sup> In Ontario the *Charitable Institutions Act* requires inspections,<sup>69</sup> as does the *Homes for Special Care Act*.<sup>70</sup> These inspections are annual and unannounced. The inspectors ensure that facilities are operating according to their contracts, relevant legislation and regulations, and standards outlined in the program manual for long-term care homes.<sup>71</sup> In Ontario, there is public reporting of inspection findings.

Traditional also throughout Canada in regard to the long-term care and residential care sectors is regulation of the structural elements of safety. Many provinces regulate facility staffing through requiring qualifications, in-house education programs, types of healthcare providers that must provide service, levels of registered nurses and rarely staff to patient ratios. For example, in New Brunswick the *General Regulation under the Nursing Homes Act* sets out standards for staff, including a reference to “staff in attendance at all times in appropriate ratios.”<sup>72</sup> In Nova Scotia, there is provision in the *Homes for Special Care Act* for regulations to be made in respect of staff requirements and qualifications.<sup>73</sup> Some guidance is provided in section 18 of the *Home for Special Care Regulations* setting out registered nurse availability and stating that homes must have sufficient staff to ensure compliance with the regulations and reasonable hours of work and holidays for the staff.<sup>74</sup> In PEI the *Nursing Home Regulations* lay out standards in regard to staffing, namely that the facility is “staffed sufficiently ... so as to provide for the resident’s safety, comfort, nursing and other care ...”.<sup>75</sup>

Standards may also be set. In Alberta, the *Nursing Homes Act* authorizes the Minister to make regulations governing “standards applicable to nursing homes, including but not limited to standards relating to the programming, design and construction of nursing homes and the care, services, drugs and medical supplies to be provided in nursing homes”.<sup>76</sup> In Manitoba, section 118.5(d) of the *Health Services Insurance Act*<sup>77</sup> permits the Minister to make regulations in relation to standards for the operation of Personal Care Homes as does the *Nursing Homes Act* in New Brunswick.<sup>78</sup> In Nova Scotia, there is provision in the *Homes for Special Care Act* for regulations respecting the standard of care and standards of accommodation.<sup>79</sup> In Ontario, the *Charitable Institutions Act*<sup>80</sup> and

<sup>67</sup> N.S. Reg. 127/1977, ss. 17(2)-(3).

<sup>68</sup> *Supra* note 59 at s. 11(2), 11(7).

<sup>69</sup> R.S.O. 1990, c.9, s. 10(1).

<sup>70</sup> R.S.O. 1990, c. H.12.

<sup>71</sup> See *Seniors’ Care: Maintaining Standards of Care in Long-term Care Homes*, online: Ontario Ministry of Health and Long-Term Care <[http://www.health.gov.on.ca/english/public/program/ltc/25\\_standards.html](http://www.health.gov.on.ca/english/public/program/ltc/25_standards.html)>.

<sup>72</sup> *Supra* note 64 at s. 18.

<sup>73</sup> *Supra* note 66 at ss. 19(k)-(l).

<sup>74</sup> *Supra* note 67 at s. 18.

<sup>75</sup> P.E.I. Reg. EC1988-10, s. 26.

<sup>76</sup> *Supra* note 60 at s. 24(1).

<sup>77</sup> *Supra* note 46.

<sup>78</sup> *Supra* note 63 at s. 29.

<sup>79</sup> *Supra* note 66 at ss. 19(q), 19 (s).

the *Homes for Special Care Act*<sup>81</sup> require the development of a care plan for each resident, and section 9.16 of the *Homes for Special Care Act* requires the development and implementation of a quality management system to monitor, evaluate and improving the quality of accommodations, care, services, programs and goods. The *Nursing Home Regulations*<sup>82</sup> of PEI lay out standards in regard to social rights and resident care.

Most provinces regulate building design and structure, the timing, quantity, and quality of meals, the safe storage and processes surrounding medication storage, dispensing and prescribing, yearly medical examinations of clients, and requirements for fire safety. For example, in Alberta the *Nursing Homes Operation Regulations*<sup>83</sup> set out requirements in regard to record-keeping, care-planning, menus, enrichment services, medical treatment, drugs and medicines. They also set out standards in respect of the operation of the nursing home in respect of electrical equipment, maintenance, hygiene and safety, and health examinations for staff. The *General Regulation* under New Brunswick's *Nursing Homes Act* sets out standards for medication administration, restraints, dietary standards and rehabilitation and activation programs, and physical standards,<sup>84</sup> and the *Nursing Home Regulations*<sup>85</sup> of PEI create standards in regard to hygiene and comfort, and safety (fire, emergencies, health of staff, medications and physician review).

### **Strengths and Weaknesses**

Quebec and Alberta both require quality related committees to be developed in certain types of facilities; this accords a degree of priority to the issue of patient safety. Ontario is addressing transparency issues by making inspectors' reports readily available to the public. These are encouraging developments. However, institutional regulation is weakly effective at best.

The principle behind licensing is that it is a tool to ensure that the applicant can provide services competently, safely, effectively and efficiently; if it cannot, then a license is not granted. There is therefore potential for licensing to be used as an inducement to comply with broader standards. However, there are problems with the traditional licensing model for hospitals or long-term care/residential facilities used in Canada. To start with, not all facilities are required to be licensed in all provinces. Considering the risks involved, this must be of concern. In addition, the traditional model of licensing used in Canada focuses on inputs, i.e. size of the rooms, number of patients, services offered. It may not focus enough attention on outputs, on the standards of services offered to consumers, or on outcomes for consumers. These factors are most likely to impact upon patient safety.

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<sup>80</sup> *Supra* note 69 at s.3.1.

<sup>81</sup> *Supra* note 70 at s. 9.15.

<sup>82</sup> *Supra* note 75.

<sup>83</sup> Alta. Reg. 258/1985, ss. 11, 15, 16, 23.

<sup>84</sup> *Supra* note 64.

<sup>85</sup> *Supra* note 75.

Inspections are an important tool to ensure compliance with basic minimum standards. However, they will likely be ineffective if notice is given, insufficient resources are devoted to the process, and standards against which inspections take place are largely input focused or are not comprehensive. An approach that relies on compliance with rules, or as Day and Klein characterize it, a deterrent approach, may not be as successful as a compliance approach where the regulator works with the regulated.<sup>86</sup> A compliance model would presuppose both time and expertise in safety, both of which are luxuries that may not be accorded inspectors.

Accreditation is completed voluntarily by most hospitals in Canada, irrespective of legislative requirements, and by some long-term care facilities. The accreditation scheme in Canada is focusing on patient safety, but it is not clear whether the standards address problems that are most important for patient safety, although they are becoming increasingly safety focused; nor is it clear that participation in the patient safety aspects of the accreditation process actually improves patient safety. However, Quebec's approach addresses the problems in relation to the lack of transparency and therefore accountability in this process by requiring publication.

The creation of accountability frameworks to clarify respective roles and responsibilities and thus accountabilities between the many actors in the health system is crucial, as without a clear account of roles and responsibilities in respect of patient safety there can be confusion, uncertainty, overlap, weakness and a lack of accountability in the programs designed to address patient safety. In addition, the clarification of roles and responsibilities is in some respects a call for action in regards to patient safety. Regulation of this type *requires* leadership by identifiable individuals, groups or organizations. Thus it creates a foundation for other regulatory initiatives to, for example, monitor patient safety, set patient safety standards, create educational priorities, and so on. On the whole there is little clear guidance about precise roles and responsibilities in regard to patient safety across the health system, and therefore little priority may be accorded to it. Accountability is therefore an issue.

Lastly, there is scope for regulators to use the power that is already granted to them by statute to make regulations that specifically address patient safety. In many provinces the potential exists but the execution is lacking. There is empirical evidence that some of the structural factors in hospitals and long-term care facilities have real effects on patient safety. For example, there is evidence in relation to duration of work hours and staff/patient mix in hospitals and long-term care facilities.<sup>87</sup> These issues are at best acknowledged by some regulators in respect of parts of the health system, but are most often left to the discretion of the health providers to initiate – this causes inconsistency.

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<sup>86</sup> Patricia Day and Rudolf Klein, "The Regulation of Nursing Homes: A Comparative Perspective" (1987) 65 *Milbank Q.* 303.

<sup>87</sup> See for example, Institute of Medicine, *Keeping Patients Safe: Transforming the Work Environment of Nurses* (Washington: National Academies Press, 2003); M. Stanton & M. Rutherford, *Hospital Nurse Staffing and Quality of Care* (Rockville, Md.: Agency for Healthcare Research and Quality, 2004); J. Needleman & P. Buerhaus, "Nurse Staffing and Patient Safety: Current Knowledge and Implications for Action" (2003) 15 *Int'l J. Qual. Healthcare* 275.

## Professional Regulation

### Introduction

A second equally important aspect of healthcare delivery is the people who provide health services – healthcare professionals. The regulation of health professionals is a provincial responsibility under the *Constitution Act, 1867*.<sup>88</sup> The chief objective of professional regulation is the protection of the public from harm. Provincial governments have adopted a model of self-regulation, in which the health professions are delegated authority via statute to administer a regulatory scheme. While schemes and delegated powers may vary from province to province and between health professions, self-regulating professions are usually given the authority to control entry into the profession and to monitor the conduct and competence of those they admit.<sup>89</sup> In general, professional self-regulatory bodies set entry requirements as to who can be registered/licensed as a professional, set standards of practice for the profession, investigate complaints and enforce standards through a disciplinary process. A number may also monitor ongoing professional competence through quality assurance mechanisms such as continuing education requirements or peer assessments.

### Regulating Health Professionals

Traditionally, government practice has been to grant each self-regulating health profession a separate statutory scheme that sets out an exclusive scope of practice, or activities the profession could perform.<sup>90</sup> For example, in the province of Nova Scotia, there are 16 different health statutes that govern 17 health professions. These were developed at different times and are generally inconsistent.<sup>91</sup> While many of these statutes have been updated, the regulatory framework is fragmented and inefficient to amend. This makes it difficult to ensure that the public are protected by the most effective regulatory provisions.<sup>92</sup>

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<sup>88</sup> *Constitution Act*, *supra* note 4 at s. 92(13).

<sup>89</sup> McNamara *et al.*, “Regulation of Health Care Professionals,” in Jocelyn Downie, Timothy Caulfield & Colleen Flood, eds., *Canadian Health Law and Policy*, 2<sup>nd</sup> ed. (Toronto: Butterworths, 2002) at 75 [McNamara].

<sup>90</sup> *Ibid* at 69; Nova Scotia Department of Health, *Health Professional Regulation Proposal for Legislative Change* (Halifax: Nova Scotia Department of Health, 2004), online: Nova Scotia Department of Health <<http://www.gov.ns.ca/health/downloads/HP%20Act%20Paper.pdf>> [Nova Scotia Department of Health].

<sup>91</sup> Nova Scotia Department of Health, *ibid.* at 2.

<sup>92</sup> *Ibid.* at 4-5.

Reforms in certain provinces, such as Ontario, British Columbia and Alberta, have focused on using umbrella legislation to create a single legislative framework that applies to all regulated health professions, which is then accompanied by separate profession-specific legislation or regulations. Coming into force on a profession-by-profession basis, Alberta's *Health Professions Act (HPA)* is umbrella legislation that sets out common rules in areas such as registration, continuing competence, complaints and discipline that will govern the province's 30 regulated health professions.<sup>93</sup> For example, under section 50(1) of the Act, all professions will be required to establish a continuing competency program that "must provide for regulated members to maintain competence and to enhance the provision of professional services." The professions will specify the details of the program in regulations they develop, which then must be approved by the government.

The legislative reforms in these provinces have also moved away from exclusive scopes of practice to a system of overlapping scopes of practice in which certain activities with higher risk are assigned to one or more professions who have the competencies required to perform them safely.<sup>94</sup> In Ontario, the *Regulated Health Professions Act (RHPA)* lists 13 controlled acts that can only be performed by members of a regulated health profession who have authorization under their profession-specific Act.<sup>95</sup> Controlled acts include communicating a diagnosis, delivering babies, prescribing drugs, administering injections and performing procedures on tissue below the dermis. In each profession-specific act, there is a brief descriptive scope of practice statement<sup>96</sup> and a list of authorized acts that specifies which controlled acts, if any, the profession may do. There are a number of exemptions and exceptions to the controlled act system, and health care services that do not involve controlled acts may be performed by anyone.<sup>97</sup> However, the Act prohibits the giving of treatment and advice by anyone other than a member of a regulated health professional working within their scope of practice when "it is reasonably foreseeable that serious physical harm may result from the treatment or advice or from an omission from them."<sup>98</sup> The *RHPA* and the profession-specific Acts also restrict the use of professional titles to members of the regulated profession. These reforms were designed to provide more flexibility in health services delivery while maintaining appropriate protections for the public.<sup>99</sup>

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<sup>93</sup> *Health Professions Act*, R.S.A. 2000, c. H-7.

<sup>94</sup> *Health Professional Regulation Proposal*, *supra* note 90 at 6; Alberta Health and Wellness, *Health Professions Act: A New Law for Regulated Health Professionals*, at 4, 11, online: Alberta Health and Wellness <[http://www.health.gov.ab.ca/resources/publications/pdf/about\\_HPA.pdf](http://www.health.gov.ab.ca/resources/publications/pdf/about_HPA.pdf)>.

<sup>95</sup> *Regulated Health Professions Act, 1991*, S.O. 1991, c.18, s.27 [*RHPA*].

<sup>96</sup> For example, the scope statement for physicians reads: "The practice of medicine is the assessment of the physical or mental condition of an individual and the diagnosis, treatment and prevention of any disease, disorder or dysfunction." *Medicine Act, 1991*, S.O. 1991, c.30, s.3.

<sup>97</sup> Health Professions Regulatory Advisory Council, *Adjusting the Balance: A Review of the Regulated Health Professions Act - A Report to the Minister of Health and Long-Term Care* (Toronto: Health Professions Regulatory Advisory Council 2001) at 18-19, online: HPRAC <<http://www.hprac.org/downloads/fyr/RHPAReport.pdf>> [HPRAC, *Adjusting*].

<sup>98</sup> *RHPA*, *supra* note 95.

<sup>99</sup> HPRAC, *Adjusting*, *supra* note 97 at 18.

Legislating requirements for entry into a health profession is the initial mechanism for ensuring members are able to provide safe, competent care. The general requirements for registration/licensure are usually set out in the Act that governs the profession, while specific details around education and training criteria set by the regulatory body are contained in regulations or by-laws. The regulatory body determines who meets the qualifications for membership and maintains a list or register of members. In Ontario, when the Registrar for a regulated health profession does not believe that the applicant meets the required standards, a panel of Registration Committee members reviews the application. The Panel may set additional training or examination requirements or place limitations or conditions on the individual's certificate of registration.<sup>100</sup> Under Ontario's *RHPA*, the public may access some information on the register, including information on the results of every disciplinary and incapacity proceeding within 6 years of the register's last update in which the member had a certificate revoked or suspended, or had terms, conditions or limitations placed it.<sup>101</sup> In Manitoba, under the *Physician Profile Regulation*, the College of Physicians and Surgeons have been required since October 31, 2005 to make available to the public a profile of every registered and licensed physician currently practicing in Manitoba.<sup>102</sup> Designed to improve transparency, the profiles include information about a doctor's education, training and current practice restrictions, as well as final disciplinary actions, medical malpractice court judgments, and convictions under certain acts occurring within the past 10 years.<sup>103</sup>

Historically, the disciplinary process dealt with cases of serious incompetence; continuing competence was viewed as a matter of professional responsibility, with some self-regulatory bodies taking on a facilitative role.<sup>104</sup> Legislation in some provinces now requires these bodies to have continuing competency or quality assurance programs aimed at ensuring high quality competent care from practicing members throughout their careers. Alberta's *Health Professions Act* will require colleges to establish a continuing competence program within five years of the Act coming into force for the profession. Each profession has flexibility in determining the specifics of its program, but programs usually will include elements such as continuing education, self-assessment or re-certification.<sup>105</sup> The *HPA* also sets out practice visits as a mechanism colleges can use as part of their continuing competence program to ensure their requirements are being met. Practice visits may involve inspecting where the member provides professional services, interviewing the member, patients, and co-workers about those services, observing the member providing services, or reviewing documents and medical records.<sup>106</sup> The Act

<sup>100</sup> *Regulated Health Professions Act, 1991*, S.O. 1991, c.18, Sch. II, s. 18(2) [*HPPC*].

<sup>101</sup> *Ibid* at c.18; HPRAC, *Adjusting*, *supra* note 97 at 88.

<sup>102</sup> *Physician Profile Regulation*, Man. Reg. 104/2005, s. 2(1).

<sup>103</sup> Certain restrictions on final disciplinary actions to be included in profiles exist. *Ibid* s. 4(1) and s. 4(4); Government of Manitoba, News Release/Communiqué, "Physician Profile Website has Been Launched" (2 November 2005), online: Government of Manitoba <<http://www.gov.mb.ca/chc/press/top/2005/11/2005-11-02-02.html>>.

<sup>104</sup> Alberta Health & Wellness, *Health Professions Act Employer's Handbook: A Guide for Employers of Regulated Health Professionals* (Edmonton: Alberta Health & Wellness, 2004) at 33, online: Alberta Health & Wellness <<http://www.health.gov.ab.ca/professionals/pdf/HPAemployersHANDBOOK.pdf>>. [Alberta Health & Wellness, *Health Professions Act*]

<sup>105</sup> *Ibid*.

<sup>106</sup> *Health Professions Act*, R.S.A. 2000, c. H-7, s. 51(3) [*HPAA*].

also makes the completion of continuing competency program requirements a condition for receiving a practice permit, a document that is generally issued annually by colleges to indicate that the member is registered and permitted to practice.<sup>107</sup> Information concerning a member's participation in a continuing competency program is confidential.<sup>108</sup> In Ontario, colleges must have in place a quality assurance (QA) committee and a QA program "to assure the quality of the practice of the profession and to promote continuing competence among the members."<sup>109</sup> Colleges have flexibility in developing the programs to be prescribed in their regulations, but the Ministry of Health and Long-Term Care guidelines specify that programs should be focused on "improved quality health care provision and improved patient outcomes."<sup>110</sup> The Ontario College of Pharmacists quality assurance program includes random practice reviews and requires members to maintain a portfolio of continuous learning activities, while the College of Physicians and Surgeons of Ontario's program uses peer assessments, physician reviews and enhancement programs.<sup>111</sup> College members must participate in QA programs and co-operate with the QA committee or its appointed assessor.<sup>112</sup>

Complaints investigations and disciplinary processes are the primary mechanisms for protecting the public from harm from practicing members. Generally, the investigation of a complaint from the public is mandatory and focuses on the gathering of evidence to determine whether to dismiss the complaint or to proceed with it to the next stage.<sup>113</sup> In Ontario, complaints are usually investigated by a panel of a College's Complaints Committee, which must have a minimum of three persons and at least one must be a public member.<sup>114</sup> Under *RHPA*, the panel has a statutory time period of 120 days to finish its investigation and provide a copy of its decision to the complainant and the member.<sup>115</sup> Regulatory bodies are increasingly using alternative dispute resolution (ADR) mechanisms to informally resolve complaints; the legislative framework for addressing these alternatives varies.<sup>116</sup> Prior to a hearing, Nova Scotia's *Medical Act* allows members to propose settlement agreements before a hearing that must be consented to by the College's legal counsel and approved by a hearing committee.<sup>117</sup> Under Alberta's *HPA*, a college's complaints director may refer the complainant and the member, with their consent, to an alternative complaint resolution process any time before a hearing is held.<sup>118</sup> The college will be required to participate in the process and any proposed settlements are subject to ratification by a complaint review committee.<sup>119</sup>

<sup>107</sup> *Ibid* at s. 38-40; Alberta Health & Wellness, *Health Professions Act*, *supra* note 104.

<sup>108</sup> *HPPA*, *supra* note 106 at s. 52(1).

<sup>109</sup> *HPPC*, *supra* note 100 at ss. 10(1), 80.

<sup>110</sup> *HPRAC*, *Adjusting*, *supra* note 97 at 93.

<sup>111</sup> Ontario Reg. 202/94, s. 42; Ontario Reg. 114/94, s. 27.

<sup>112</sup> *HPPC*, *supra* note 100 at s. 82 (1).

<sup>113</sup> McNamara, *supra* note 89 at 79.

<sup>114</sup> *HPPC*, *supra* note 100 at s. 25(2).

<sup>115</sup> *Ibid* at ss. 27-28.

<sup>116</sup> Ed. Schollenberg, "Licensing and Regulation of Health Professions" in M. J. Dykeman, ed., *Canadian Health Law Practice Manual*, looseleaf (Toronto: Butterworths, 2000) [Schollenberg].

<sup>117</sup> *Medical Act*, S.N.S 1995-96, c.10, s.57.

<sup>118</sup> *Health Professions Act*, R.S.A. 2000, c. H-7, s. 58 (1).

<sup>119</sup> *Ibid* at ss. 58(2), 60(2).

Self-regulatory bodies generally impose sanctions for behaviors that constitute professional misconduct,<sup>120</sup> incompetence<sup>121</sup> or incapacity,<sup>122</sup> although the processes for dealing with them may vary. In Ontario, the complaints committee refers complaints of professional misconduct and incompetence to the Discipline Committee, whose hearings are public subject to certain exceptions.<sup>123</sup> A panel of three to five Disciplinary Committee members, two of whom must be public members, hears the case.<sup>124</sup> Complaints or reports concerning a member's incapacity are sent to the Executive Committee, who may appoint a Board of Inquiry, which has the power to require a member undergo physical or mental examinations.<sup>125</sup> The matter can then be referred to a Fitness to Practice Committee, which conducts closed hearings to determine whether the member's certificate of registration should be revoked, suspended, or subject to conditions. Traditionally, complainants do not have party status in disciplinary hearings, and the self-regulatory body's representative will bring its case against the member. However, legislation can prescribe certain circumstances where complainants may be able to participate.<sup>126</sup> Penalties a disciplinary panel can impose may include reprimands, mandatory education, fines, conditions on a license, or its loss or suspension.<sup>127</sup> Most statutes provide the member with the right to appeal a negative finding to a court.<sup>128</sup> A complainant in Ontario can appeal certain decisions of the Complaints Committee to the Health Professions Appeal and Review Board (HPRAB), which will review the adequacy of the Complaints Committee investigation and/or whether the Committee's decision was reasonable.<sup>129</sup> Under Alberta's *HPA*, any person will be able to take concerns about college processes and outcomes to the provincial Ombudsman after all formal or informal appeal mechanisms within the college have been exhausted.<sup>130</sup> The Ombudsman does not act as a formal appeal body, but may make recommendations to the college concerned.

## Strengths and Weaknesses

As a general comment, the Canadian legal framework used to regulate health professionals varies from province to province and profession to profession. The movement to umbrella legislation in British Columbia, Alberta and Ontario provides

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<sup>120</sup> Professional misconduct usually refers to unacceptable conduct, such as the sexual abuse of a patient. In Ontario, professional misconduct is defined both in section 51 of the *RHPA* and in regulations specific to each profession. For further discussion of term and how it is used in Canada, see Schollenberg, *supra* note 116.

<sup>121</sup> Incompetency generally means a lack of skill, knowledge or judgment at a level that constitutes unsafe practice. See *HPPC*, *supra* note 100 at s. 52(1).

<sup>122</sup> Incapacity usually refers to a mental, physical or emotional illness or addiction that impairs the practitioners ability to practice safely. See the definition of "incapacitated" in *HPPA*, *supra* note 106 at s. 1(1)(s).

<sup>123</sup> *HPPC*, *supra* note 100 at ss. 26(1), 45.

<sup>124</sup> *Ibid* at s. 38(2).

<sup>125</sup> *Ibid* at s. 59(2).

<sup>126</sup> *Ibid* at s. 41(1).

<sup>127</sup> McNamara, *supra* note 89 at 78.

<sup>128</sup> Schollenberg, *supra* note 116 at s. 4.156.

<sup>129</sup> HPRAC, *Adjusting*, *supra* note 97 at 71.

<sup>130</sup> *HPPA*, *supra* note 106 at s. 127; Alberta Health & Wellness, *Health Professions Act*, *supra* note 104.

enhanced consistency across all regulated health professions in terms of the protections available to the public. The replacement of exclusive scopes of practice in these provinces, with a system of overlapping scopes of practice with controlled high-risk activities, reflects a broader shift from profession-centered to public interest regulation.

The primary focus of the regulation of health professionals is the protection of the public. As McRuer states, “The public has a genuine and very real interest in knowing that members of the self-governing bodies are properly trained and have good ethical standards.”<sup>131</sup> To that can also be added good practicing standards and assuring health professionals continued competence in their profession. However, health professional regulation struggles between two competing priorities, ridding the profession of ‘bad apples’ and facilitating the practice of individual professionals. The inherent tension is between professional demands for support and public and media demands for someone to be at fault. The patient safety movement suggests that the current system focuses too much on establishing blame for individual incidents abstracted from their context. Accountability mechanisms should be available for particularly egregious acts, but the movement suggests that more attention needs to be paid to developing systems to effectively prevent harm rather than to react to harms that have already occurred. This view is echoed by the professions. The National Steering Committee on Patient Safety noted in its report that there exists a perception among health professionals that regulatory bodies are more focused on removing bad apples than improving practice and that the regulatory process requires a greater emphasis on continuous improvement through education and remediation rather than blame and punishment.<sup>132</sup> In contrast, the ability of professional self-regulation to protect the public from harm has been the subject of increasing criticism.<sup>133</sup> There is a perception within the public that self-regulatory bodies tend to protect members of the profession and there exists “an inappropriate unwillingness to report or act upon the incompetent or unethical behavior of colleagues.”<sup>134</sup> What is clear from this divide is that there needs to be available to the self-regulating health professions more flexible ways of addressing issues with the practice of individuals that address patient safety concerns of patient protection but also minimize, where appropriate, the punitive nature of the process. Current disciplinary mechanisms do serve important accountability and safety functions, however. A movement towards public disciplinary processes also affords a certain amount of transparency to the process, to the determinations made by the disciplinary panel and to public awareness of the incidence and experience of unsafe treatment or care.

In addition, the move towards interdisciplinary practice exposes a weakness in current disciplinary systems in that these systems are not equipped to address broad systemic issues nor the complexities of multi-disciplinary practice. Currently, multiple professions

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<sup>131</sup> Ontario, *Royal Commission of Inquiry into Civil Rights (McRuer Report)*, vol. 3 (Toronto: Queen’s Printer, 1968-1971) (Commissioner: James Chalmer McRuer).

<sup>132</sup> National Steering Committee, *supra* note 21 at 15.

<sup>133</sup> C. Flood & T. Epps, “Waiting for Health Care: What Role for a Patients’ Bill of Rights?” (2004) 49 McGill L.J. 515 at 525 [Flood].

<sup>134</sup> Manitoba Law Reform Commission, *Discussion Paper: The Future of Occupational Regulation in Manitoba* (Winnipeg: Law Reform Commission, 1993) at 42. HPRAC Adjusting, *supra* note 97.

and bodies may potentially investigate a single incident. This creates inefficiencies, both fiscal and in terms of effectiveness of the investigation of the incident. A single collaborative review mechanism capable of identifying individual and/or system factors at work may be useful.<sup>135</sup>

Self-regulatory bodies that lack public confidence and trust are less effective at protecting the public from harm, as the public is less willing to report their concerns.<sup>136</sup> Ontario's Health Professions Regulatory Advisory Council (HPRAC), a statutory body created under *RHPA* with a mandate to provide policy advice to the Minister on the regulation of health professionals, has called for greater transparency, accountability, and patient and public involvement in Ontario's regulatory framework in order to improve its effectiveness.<sup>137</sup> Its recommendations include a provision mandating that the professional members of a College's governing body must equal the number of public members plus a maximum of two, giving party status to complainants at disciplinary hearings, expanding the information accessible to the public on the register, and making such accessibility mandatory.<sup>138</sup> Enhanced transparency and accountability mechanisms in the system, such as annual reports to government and the public, would allow for improved monitoring of governing bodies and the activities they undertake to protect the public.

Manitoba's physician profile regulation has the potential to increase patient safety, as the added transparency will increase the ability of the public and physicians making referrals to assess the qualifications of physicians and hold them accountable. However, public reporting of physician competence is not without its critics. There may be consequences in respect of the equitable treatment accorded to patients by physicians, unless outcome data is risk adjusted. In addition, this type of process may be seen to be unduly punitive and may discourage learners.

Important proactive mechanisms towards assuring patient safety are quality assurance and continuing competency programs. Mandating quality assurance and continuing competency programs in Alberta and Ontario requires self-governing bodies to create ongoing mechanisms aimed at maintaining the competency and safe practice of health professionals throughout their career. This in turn serves valuable patient safety ends.

While there has been movement towards developing quality assurance and continuing competency programs for health professionals in Canada, there is a lack of literature and "little evidence of implementation and few evaluations" of programs in this area.<sup>139</sup> While recognizing the importance of continuing education components in QA programs,

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<sup>135</sup> National Steering Committee, *supra* note 21 at 15. See HPRAC, *Adjusting*, *supra* note 97 at 97-102 where, in their 2001 report, HPRAC indicated that some support was expressed for empowering colleges to identify and report practice setting or systemic issues. HPRAC did not recommend using *RHPA* as a mechanism for addressing broader quality of care issues in the health system, but rather setting up a taskforce on system errors.

<sup>136</sup> HPRAC, *Adjusting*, *ibid.* at 16.

<sup>137</sup> *Ibid.* at 17.

<sup>138</sup> *Ibid.* at 125-133.

<sup>139</sup> Health Professions Regulatory Advisory Council, *Executive Summary* (Sept 2005), online: HPRAC <<http://www.hprac.org/downloads/sep05/ExecutiveSummary-Sept26.pdf>>.

a HPRAC report on the effectiveness of Ontario Colleges' QA programs in October 2000 held that practice assessments were the "most objective and rigorous evaluation approach" for assessing competency.<sup>140</sup> Colleges experienced significant resistance to practice assessments, which were viewed by some members to be "invasive, costly and time consuming."<sup>141</sup> Unclear about the objectives of practice assessments, some Colleges viewed them "as a deterrent or punishment for worst practices."<sup>142</sup>

## Products Regulation

### Introduction

Since the international outcry over the birth defects resulting from Thalidomide, drugs and devices have been regulated in all countries to ensure safety. Canada has a framework for the regulation of drugs and devices both pre- and post-marketing.

The regulation of food, drugs and devices falls within the federal government's jurisdiction as it falls within the federal government's criminal law power.<sup>143</sup> Because medical products are often intended for bodily ingestion or implantation, the risks of which can be substantial, the Supreme Court of Canada has described the relationship between medical products and the public as an intimate one.<sup>144</sup> This intimate relationship requires trust on the part of health care consumers that medical products will be beneficial, not harmful (or at least more beneficial than harmful). The risk of harm provides the reason for government regulation of medical products.<sup>145</sup>

In Canada, the legislation regulating medical products is the *Food and Drugs Act*,<sup>146</sup> a federal statute administered by Health Canada. Two sets of regulations under the *Act* designed to protect the health and safety of the public are relevant here: the *Medical Devices Regulations*<sup>147</sup> and the *Food and Drug Regulations*.<sup>148</sup> The regulatory regime in Canada is intended to regulate both pre-market and post-market activities of

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<sup>140</sup> Practice assessment components include self-assessment of practice, patient questionnaires, comments from peers and supervisors, and onsite peer reviews. See Health Professions Regulatory Advisory Council, *Report to the Minister of Health and Long-term Care: Effectiveness of Colleges' Quality Assurance Programs* (Toronto: HPRAC, 2000) at 8 online: HPRAC <<http://www.hprac.org/downloads/qualityassurance/QaHPRAC.pdf>>

<sup>141</sup> *Ibid.* at 8.

<sup>142</sup> *Ibid.* at 17.

<sup>143</sup> *R. v. Wetmore*, [1983] 2 S.C.R. 284.

<sup>144</sup> *Hollis v. Dow Corning Corp.* (1995), 190 N.R. 241 (S.C.C.) at para. 25.

<sup>145</sup> Auditor General of Canada, *Report of the Auditor General of Canada to the House of Commons*, (Ottawa: Office of the Auditor General of Canada, 2004) c. 2 at 4 [Auditor General].

<sup>146</sup> R.S.C. 1985, c. F-27.

<sup>147</sup> *Medical Devices Regulations* S.O.R./1998-282.

<sup>148</sup> *Food and Drug Regulations*, C.R.C., c. 870.

manufacturers, importers and sellers of medical products to ensure safety, effectiveness and high quality.

### **Food and Drugs Act**

The *Food and Drugs Act* creates an inspection scheme for manufacturers, importers, etc, to ensure compliance with the Act and its regulations. There are no requirements set out in the legislation about when inspections should be undertaken.

The policy document, *Guidance on the Medical Device Inspection Program*, states that “compliance with safety and effectiveness requirements is not routinely assessed during an inspection.”<sup>149</sup>

### **Medical Devices Regulations**

The *Medical Devices Regulations* apply to medical devices intended for human use. These regulations impose requirements in relation to labeling, advertising, obtaining licences to sell, maintaining distribution records and records of complaint, implant registration, reporting adverse events and recall.

### **Safety**

The regulations assign primary responsibility for safety to manufacturers: “a manufacturer shall ensure that the medical device meets the safety and effectiveness requirements.”<sup>150</sup> It also states that:

A medical device shall be designed and manufactured to be safe, and to this end the manufacturer shall, in particular, take reasonable measures to:

- (a) identify the risks inherent in the device;
- (b) if the risks can be eliminated eliminate them;
- (c) if the risks cannot be eliminated
  - (i) reduce the risks to the extent possible
  - (ii) provide for protection appropriate to those risks including the provision of alarms; and
  - (iii) provide, with the device, information relative to the risks that remain; and
- c) minimize the hazard from potential failures during the projected useful life of the device.<sup>151</sup>

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<sup>149</sup> Health Canada, *Guidance on the Medical Device Inspection Program* (Ottawa: Health Canada, 2004) at s. 4.2.1., online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/md\\_insp\\_prog-prog\\_insp\\_mm\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/md_insp_prog-prog_insp_mm_tc-tm_e.html)>.

<sup>150</sup> *Medical Devices Regulations*, *supra* note 147.

<sup>151</sup> *Ibid.* at s. 10.

## *Licensing*

Manufactured devices intended for sale are categorized into four classes of risk, from low risk (Class I) to high risk (Class IV). Depending on the risk class of a device, the pre-market regulatory requirements are more or less rigorous. Devices in the higher risk Classes II, III and IV must be licensed before importation or sale.<sup>152</sup> The upper risk categories of Class III or IV must provide the specified documentation about the design and manufacture of the device as part of the application for a license to sell (Class II must provide the same information in respect only to the manufacturing process in its application).

Class II, III, IV must provide:

- a list of complied with standards to satisfy safety and effectiveness requirements;
- a quality system certificate issued by a third party registrar approved by Health Canada verifying that the quality systems in place comply with standards.<sup>153</sup>

Class III also must provide:

- a bibliography of all published reports dealing with the use, safety and effectiveness of the device;
- a summary of all studies on which the manufacturer relies to ensure the device meets safety and effectiveness requirements and the conclusions drawn from those studies.

Class IV must also provide:

- a risk assessment;
- a quality plan;
- detailed information on all studies on which the manufacturer relies on to meet safety and quality requirements;
- a summary of investigational (human subject) trials and the conclusions drawn.
- a bibliography of all published reports dealing with the use, safety and effectiveness of the device.

Certification must be renewed through audits every three years and annual surveillance audits are also conducted.

If the Minister is satisfied that the device meets safety and effectiveness requirements, the Minister must license the device. He or she can set terms and conditions, including tests to be performed and a requirement to submit the results. He or she can also request further information. The Minister may also suspend the license if, amongst other things,

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<sup>152</sup> *Ibid.* at s. 26.

<sup>153</sup> *Ibid.* at ss. 32(3)-(4).

there are reasonable grounds to believe that the device no longer meets safety and quality requirements or the quality system is inadequate.<sup>154</sup>

Class I devices do not require licensing. However, if on reasonable grounds the Minister believes that a Class I device does not meet safety and effectiveness requirements, the Minister may require further information from the manufacturer and may direct the manufacturer to stop the sale of the device if the manufacturer does not comply with safety and effectiveness requirements.<sup>155</sup>

### ***Clinical Trials***

Regarding pre-market activities in particular, in order to conduct clinical trials testing the use of medical devices on humans, manufacturers require governmental authorization prior to testing. Applications are examined before permission to proceed is given. During the clinical trials, all serious adverse events occurring during the trials must be reported to Health Canada and records must be kept.<sup>156</sup>

### ***Adverse Events Reporting***

Among required post-market activities for medical devices, it is mandatory for manufacturers and importers to report any incident involving failure or deterioration of a device, or any inadequacy in labeling or directions for use, occurring inside or outside Canada or involving a device sold in Canada, which has led to death or serious deterioration of the health of a person.<sup>157</sup> They must submit a preliminary report within 10 days (death or serious deterioration) or 30 days (potential for death or serious deterioration) containing, amongst other things, preliminary conclusions and an investigation plan. A final report must also be submitted once complete, detailing the incident, the cause, any justification, and actions taken, if any.

### ***Reactive Measures***

The legislation requires that the manufacturer, importer or distributor keep records of reported problems, including consumer complaints and the actions taken to address the problems.<sup>158</sup>

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<sup>154</sup> *Ibid.* at s. 40.

<sup>155</sup> *Ibid.* at s. 25.

<sup>156</sup> *Ibid.* at s. 80.

<sup>157</sup> *Ibid.* at s. 59.

<sup>158</sup> *Ibid.* at s. 57.

It is mandatory for manufacturers to provide registration cards with implant devices so that the manufacturer can locate patients to advise them of any new information or a recall regarding the implant.<sup>159</sup>

## **Food and Drug Regulations**

The *Food and Drug Regulations* (Part C) regulate drug products. These regulations set out, among other things, requirements respecting labeling, licensing, using cautionary statements, child restraint packaging, and record keeping, as well as requirements governing prescriptions, prescription drugs, non-prescription drugs, clinical trials involving human subjects, adverse drug reaction reporting and recall. The regulations include Good Manufacturing Practices for fabricating, packaging/labeling, testing and storing drugs.<sup>160</sup>

### ***Licensing***

Before a person can import, fabricate, package/label, distribute, wholesale or perform clinical trials they must have a license. Applicants are required to provide evidence that buildings, equipment, proposed practices and procedures comply with the specific requirements set out in Divisions 2-4 of the Act. The Minister may require further information and may set terms and conditions of licensure. The Minister may also suspend a license without notice if necessary to prevent injury to the health of the consumer.<sup>161</sup>

No new drug may be sold in Canada until a new drug submission has been filed with the Minister, the submission is held to be satisfactory, and a notice of compliance is issued.<sup>162</sup> The applicant must provide sufficient information for the Minister to assess its safety and effectiveness.

### ***Clinical Trials***

Authorization is required to conduct clinical trials of drugs.<sup>163</sup> An application for authorization to import a drug to be used in a clinical trial must, according to the regulations:

- be signed and dated by the sponsor's senior medical or scientific officer in Canada and senior executive officer;

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<sup>159</sup> *Ibid* at s. 66.

<sup>160</sup> *Food and Drug Regulations*, *supra* note 148 at Part C, Div. 2.

<sup>161</sup> *Ibid.* at c.01A.017.

<sup>162</sup> *Ibid.* at Div. 8.

<sup>163</sup> *Ibid.* at Part C, Div. 5.

- include a copy of the protocol for the clinical trial;
- a statement that will be set out in each informed consent form stating the risks and anticipated benefits to the health of clinical trial subjects as a result of their participation in the clinical trial;
- a clinical trial attestation, signed by the sponsor's senior medical or scientific officer in Canada and senior executive officer. It must contain: the title of the protocol and the clinical trial number; the brand name; the chemical name or the code for the drug; the therapeutic and pharmacological classifications of the drug; the medicinal ingredients of the drug; the non-medicinal ingredients of the drug; the dosage form of the drug; the contact information for the sponsor or the sponsor's representative in Canada; for each clinical trial site the qualified investigator's contact information, (if known when submitting the application); for each clinical trial site; the contact information of the research ethics board that approved the protocol and informed consent form (if known at the time of submitting the application); a statement that the clinical trial will be conducted in accordance with good clinical practices and the Regulations; and that the application is complete and accurate and is not false or misleading;
- the contact information of any research ethics board that has previously refused to approve the protocol, its reasons for doing so and the date on which the refusal was given, (if known);
- an investigator's brochure that contains the following information:
  - (i) the physical, chemical and pharmaceutical properties of the drug,
  - (ii) the pharmacological aspects of the drug, including its metabolites in all animal species tested,
  - (iii) the pharmacokinetics of the drug and the drug metabolism, including the biological transformation of the drug in all animal species tested,
  - (iv) any toxicological effects in any animal species tested under a single dose study, a repeated dose study or a special study in respect of the drug,
  - (v) any results of carcinogenicity studies in any animal species tested in respect of the drug,
  - (vi) any results of clinical pharmacokinetic studies of the drug,
  - (vii) any information regarding drug safety, pharmacodynamics, efficacy and dose responses of the drug that were obtained from previous clinical trials in humans, and
  - (viii) if the drug is a radiopharmaceutical information regarding directions for preparing the radiopharmaceutical, the radiation dosimetry in respect of the prepared radiopharmaceutical and a statement of the storage requirements for the prepared radiopharmaceutical;
- if the drug contains a human-sourced excipient, including any used in the placebo,
  - (i) information that indicates the human-sourced excipient has been assigned a drug identification number or, if it is a new drug, issued a notice of compliance, or
  - (ii) sufficient information to support the identity, purity, potency, stability and safety of the human-sourced excipient;
- if the drug has not been assigned a drug identification number or a notice of compliance the chemistry and manufacturing information in respect of the drug, including its site of manufacture; and

- the proposed date for the commencement of the clinical trial at each clinical trial site (if known).<sup>164</sup>

The drug may be imported for the purpose of a clinical trial if:

- an application has been submitted;
- the Minister does not refuse the application (within 30 days);
- a Research Ethics Board at each clinical trial site has approved the study protocol and the informed consent form; and
- the sponsor provides the Minister with all information about the investigators and clinical trial sites if that information was not available when the application was submitted.<sup>165</sup>

The Minister may refuse approval if:

- the application was not complete;
- the information provided was insufficient to enable an assessment of the safety and risks of the drug or the clinical trial, or
- the Minister believes that the drug will endanger the health of participants in the trial or other people or it is contrary to the best interests of the clinical trial subject or the objectives of the clinical trial will not be achieved.<sup>166</sup>

The Regulations also set requirements for Good Clinical Practices.<sup>167</sup> According to the Regulations, every sponsor must ensure that a clinical trial is conducted in accordance with good clinical practices and will ensure that:

- (a) the clinical trial is scientifically sound and clearly described in a protocol;
- (b) the clinical trial is conducted, and the drug is used, in accordance with the protocol and the Regulations;
- (c) systems and procedures that assure the quality of every aspect of the clinical trial are implemented;
- (d) for each clinical trial site, the approval of a research ethics board is obtained before the clinical trial begins at the site;
- (e) at each clinical trial site, there is no more than one qualified investigator;
- (f) at each clinical trial site, medical care and medical decisions, in respect of the clinical trial, are under the supervision of the qualified investigator;
- (g) each individual involved in the conduct of the clinical trial is qualified by education, training and experience to perform his or her respective tasks;
- (h) written informed consent, given in accordance with the applicable laws governing consent, is obtained from every person before that person participates in the clinical trial but only after that person has been informed of
- (i) the risks and anticipated benefits to his or her health arising from participation in the clinical trial, and

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<sup>164</sup> *Ibid.* at c.05.005.

<sup>165</sup> *Ibid.* at c.05.006.

<sup>166</sup> *Ibid.*

<sup>167</sup> *Ibid.* at Part C, Div. 5, c.05.010.

- (ii) all other aspects of the clinical trial that are necessary for that person to make the decision to participate in the clinical trial;
- (i) the requirements respecting information and records are met; and
- (j) the drug is manufactured, handled and stored in accordance with the applicable good manufacturing practices.

Health Canada inspects clinical trial sites and trial sponsors to ensure that the generally accepted principles of good clinical practice are met. The objectives of the inspection are to ensure that participants in clinical trials are not subjected to undue risks, to validate the quality of the data generated, or to investigate complaints. Up to two percent of clinical trial sites will be subject to pre-announced inspections each year. Inspectors will examine current and past clinical trials. The Minister will use the information collected as a result of these inspections to ensure compliance with the regulatory framework and will take enforcement action, when deemed necessary. If a regulated party does not respond voluntarily to requests from the Inspectorate to comply with regulations, the following measures can be considered: customs activities, injunction, prosecution, forfeiture, public warning or advisory, letters to trade and regulated parties, regulatory stop-sale, search and seizure, seizure and detention, suspension or cancellation of marketing authorization/product licences, refusal, suspension or amendment of establishment licence and a warning letter.<sup>168</sup>

Any serious unexpected adverse drug reaction must be reported to the Minister, within seven days if it is fatal or life-threatening, or within 15 days for neither fatal nor life-threatening events.<sup>169</sup> A report must also be made within 15 days if a clinical trial is discontinued and a reason(s) must be provided. The Minister must also suspend clinical trials if the Minister has reasonable grounds to believe that the regulations or Act has been contravened, information provided is false and misleading or there has been a lack of compliance with good clinical practices or a failure to provide information or samples. The Minister may also suspend the trial if there are reasonable grounds to believe that it is necessary to do so to prevent injury. These provisions are very rarely used and a routine inspectorial scheme has not been implemented.<sup>170</sup>

### ***Adverse Drug Reaction Reporting***

Manufacturers are not permitted to sell a drug unless they report within 15 days any serious adverse drug reaction that happened within Canada and any serious unexpected adverse drug reaction that took place outside Canada.<sup>171</sup> Such reports can now be made over a internet based reporting system. Manufacturers must also submit on an annual basis a summary report of adverse drug reactions associated with a drug. Although

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<sup>168</sup> Health Canada, Policy and Strategic Planning Directorate, *Compliance and Enforcement Policy (POL-0001), Version 2* (Ottawa: Health Canada, 2005), online: HC <[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol\\_1\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm_e.html)> [Health Canada, *POL-001*].

<sup>169</sup> *Food and Drug Regulations*, *supra* note 148 at Part C, Div. 5, c.05.014.

<sup>170</sup> Health Canada, *Regulatory Impact Analysis Statement – Regulations Amending the Food and Drug Regulations (1024 – Clinical Trials)* (Ottawa: Health Canada).

<sup>171</sup> *Food and Drug Regulations*, *supra* note 148 at c.01.016.

manufacturers are required to report adverse reactions, reporting is voluntary for health professionals and consumers. Health Canada believes the number of reports it receives from these groups reflects less than 10% of adverse reactions.<sup>172</sup> In 2005, Health Canada sought public responses to a proposal to make mandatory the reporting of adverse drug reactions by physicians.

The Canadian Adverse Drug Reaction Monitoring Program (CADRMP) adverse reaction database contains reports submitted to the program concerning suspected adverse reactions that happened in Canada or that involved Canadian marketed health products.<sup>173</sup> Reporters of adverse events receive an acknowledgement and monthly updates from Regional Adverse Reaction Centres. Health Canada publishes a newsletter for health professionals and the public with information on suspected adverse reactions. The information on the database became publicly accessible in 2005, after the Canadian Broadcasting Corporation made it publicly available on its website.<sup>174</sup>

Health Canada analyses these reports and selected foreign reports. It may then, if warranted, undertake a comprehensive re-assessment of the risk/benefit profile of a product. If Health Canada identifies a safety issue, it may take appropriate action. Actions range from distributing new product safety information to the public and/or the health care community, to recommending changes to the product's labeling, or requesting the removal of the product from the market. In 2004, Health Canada implemented a new post-market inspection strategy for drugs marketed in Canada pursuant to sections 23 and 24 of the *Food and Drugs Act*.<sup>175</sup> The inspectors are to assess compliance with the regulation relating to the reporting of adverse drug reactions and requirements for reporting failure in efficacy of new drugs. Inspections are undertaken as required or on a multi-year cycle and will be undertaken at the same time as inspections in relation to good manufacturing practices. The inspectorate is to provide information and encourage 'voluntary compliance'.<sup>176</sup> Responses are required from manufacturers to the observation of an inspectorate report within a specified (but undetermined) time and they are given the opportunity to become compliant, if they do not accept that opportunity, where necessary, the inspectorate will consider enforcement options. The Inspectorate chooses what enforcement measure to undertake based on the following principles:

- risk to health and safety;
- the manufacturer's compliance history;

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<sup>172</sup> Health Canada, "MedEffect," online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/medeff/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/index_e.html)>.

<sup>173</sup> Health Canada, "Canadian Adverse Drug Reaction Monitoring Program (CADRMP) Adverse Reaction Database," online: Health Canada <[http://www.hc-sc.gc.ca/dhp-mps/medeff/databasdon/agreement\\_accord\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/databasdon/agreement_accord_e.html)>.

<sup>174</sup> Canadian Broadcasting Corporation, "Faint Warning: Three Case Studies" *CBC Radio* (2004), online: CBC <<http://www.cbc.ca/news/adr/personal/>> [CBC, "Faint"]; 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/>> [Moore].

<sup>175</sup> Health Canada, Health Products and Food Branch Inspectorate, *Inspection Strategy for Post-Market Surveillance (PO- 0041)* (Ottawa: Health Canada, 2004) online: HC <[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol\\_41\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/docs/pol_41_tc-tm_e.html)>.

<sup>176</sup> *Ibid.*

- the degree of indifference or premeditation;
- likelihood of reoccurrence;
- likelihood of enforcement being effective;
- need to maintain public confidence;
- the priorities and resources of the Inspectorate.<sup>177</sup>

## Strengths and Weaknesses

Regulation of drugs and devices plays a necessary and valuable role in ensuring that drugs and devices are safe for patients to use. It is an important mechanism to set standards for drugs and devices and their design, manufacture, trials and use, and to monitor and react to signals that the risks associated with a particular drug or device are too high and the drug should be withdrawn from the market. However, the model currently in use in Canada is not without its weaknesses.

### *Medical Devices*

A report of the Auditor General of Canada in 2004 analyzed the work of Health Canada in administering the *Medical Devices Regulations*.<sup>178</sup> The Report concluded:

As a result of the gaps in its Medical Devices Program, Health Canada does not have a comprehensive program to protect the health and safety of Canadians from risks related to medical devices, even though it committed to such a program over a decade ago. Its failure to deliver such a program compromises Health Canada's ability to protect health and safety, which could translate into a growing risk – risk of both injury and liability.<sup>179</sup>

Regarding weaknesses, the Auditor General's report determined there was need to better manage risks after products are on the market,<sup>180</sup> suggesting:

- improved inspection for regulatory compliance by manufacturers to such things as distribution records, responses to complaints and adverse events and selling only licensed devices;<sup>181</sup>
- increased vigilance regarding the sale of unlicensed medical devices by using logos or bar codes to identify licensed devices and penalizing those who sell unlicensed devices;<sup>182</sup>

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<sup>177</sup> Health Canada, *POL-0001*, *supra* note 168.

<sup>178</sup> Auditor General, *supra* note 145.

<sup>179</sup> *Ibid.* at 2.1.

<sup>180</sup> *Ibid.* at 1.

<sup>181</sup> *Ibid.* at 19.

<sup>182</sup> *Ibid.* at 20.

- an improved surveillance system for collecting adverse events from health care professionals and patients after medical devices are in use, together with better analysis and interpretation of adverse events;<sup>183</sup>
- an improved system for registering implant devices since registration cards containing contact information used to locate patients are not always completed;<sup>184</sup>
- introduction of new regulations covering the reprocessing and reuse of devices that are intended for single use only since there is information that single use devices are being reused to save costs;<sup>185</sup>
- a greater investment of resources to deliver the program;<sup>186</sup>
- greater monitoring of clinical trials and verification of the quality and integrity of the results of the trials;<sup>187</sup>
- post-market inspection to assure that manufacturers or importers are operating adequate surveillance systems, taking appropriate action in response to adverse events or complaints, and reporting all serious adverse events to Health Canada;
- improved communication of concerns to health providers, as those surveyed by the Auditor suggested that communications were not timely.

Health Canada agreed to undertake corrective action in respect of these issues.

### ***Food and Drug Regulations***

Drug regulation has been occurring for some years now and claims some success with the detection and withdrawal of certain drugs from the market. However, rates of adverse events remain consistently high, or are increasing, leading some to question the effectiveness of the current programs in effecting measurable change in respect of the safety of patients. Some critics argue that the focus of regulatory schemes on reporting and identification of problems ignores the crucial importance of managing and preventing adverse events.<sup>188</sup> Information is not being adequately communicated to providers, who are also given little support in managing issues relating to adverse events in general, and specific medications and treatment regimes in particular. Without this aspect being addressed, regulatory schemes, it is argued, are ineffective.

In addition, it is argued that Health Canada gets too little information provided to it by manufacturers, and drugs are tested on too few people who are not representative of the community at large, making it difficult to accurately assess risk and thus safety. Critics note that manufacturers may release the results of clinical trials only selectively to the public, and sometimes perhaps to regulators, so findings that support manufacturers'

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<sup>183</sup> *Ibid.* at 22.

<sup>184</sup> *Ibid.* at 24.

<sup>185</sup> *Ibid.* at 26.

<sup>186</sup> *Ibid.* at 2.

<sup>187</sup> *Ibid.* at 2.47.

<sup>188</sup> E. Roughead, "Managing Adverse Drug Reactions: Time to Get Serious" (2005) 182 M.J.A. 264.

claims are widely disseminated and unfavorable reports withheld.<sup>189</sup> Critics also note a tendency for drug companies to use a variety of pressure tactics to prevent unfavorable reports about their products being made public.<sup>190</sup>

Many of the criticisms leveled at the regulatory scheme relating to devices are equally valid for drugs. There is little or no monitoring of post-market surveillance programs. There are criticisms of the adverse reactions reporting program and database, with critics arguing that it is not timely enough in responding to trends, there are not enough resources devoted to investigating the reports that are currently filed, and the system as a whole receives too few reports, rendering it impossible to accurately reflect the extent of possible harms. 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.<sup>191</sup> The regulatory program as a whole is under-funded and therefore cannot be more proactive. In addition, politicians, who in the 2004 Speech from the Throne committed Health Canada to approving drugs more quickly, are not also making a public commitment to ensuring safety during this process. When there are limited resources devoted to the regulation of drugs, resources may be diverted from safety, or not assigned to safety, to guarantee speed. Commentators note that ‘faster’ does not necessarily equate with ‘effective’ nor is it efficient if a drug is subsequently withdrawn because of harmful side effects.<sup>192</sup> With the commitment to speeding up drug approvals, there was no concurrent commitment to assuring the safety of Canadians who use drugs and devices.

There are also serious concerns in relation to transparency and accountability in respect of drug regulation and presumably also the regulation of medical devices. The actual process of licensing a drug, and for that matter a device, has until relatively recently been shrouded in secrecy and still is under the shroud for the most part. For example, consumers and health providers were not permitted direct access to the adverse events database until 2005.

Secrecy in processes gives rise to at least two significant issues. First is the issue of patient safety. Researchers and interested parties are still unable to access the information used to approve new drugs in Canada, as the information is deemed commercially sensitive and therefore confidential under the *Access to Information Act*.<sup>193</sup> Critics argue that the non-release of safety and efficacy information does not allow the

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<sup>189</sup> David Hailey, “Scientific Harassment by Pharmaceutical Companies: Time to Stop” (2000) 162 C.M.A.J.

<sup>190</sup> *Ibid.* See also Jon Thompson, Patricia Baird, & Jocelyn Downie, *The Olivieri Report: The Complete Text of the Report of the Independent Inquiry Commissioned by the Canadian Association of University Teachers* (Toronto: James Lorimer & Co., 2001).

<sup>191</sup> CBC, “Faint,” *supra* note 174; Moore, *supra* note 74; Canadian Broadcasting Corporation, “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](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>>.

<sup>192</sup> Janice Graham, “Smart Regulation: Will the Government’s Strategy Work?” (2005) 173 C.M.A.J. 1469.

<sup>193</sup> Joel Lexchin & Barbara Mintzes, “Transparency in Drug Regulation: Myth or Oasis?” (2004) 171 C.M.A.J. 1503.

non-published scientific data to be available to the scrutiny of independent scientists. This therefore can potentially lead to inappropriate prescribing and use and therefore unsafe treatment and care. In response, Health Canada now publishes a Summary Basis of Decision outlining the reasons for the decision to approve the drug. However, researchers have demonstrated that on some occasions the data presented to the regulator (often interim results but not presented as such) and the data subsequently published (final results) are different. Researchers also established that it was not possible for independent scientists to establish such results using the Health Canada document.<sup>194</sup> Health Canada does not contest the data provided to it and by keeping it confidential also requires the public to accept its judgment about the safety and effectiveness of the drug.

Second, a 2000 report into drug review processes suggested that:

[I]n our view and that of many stakeholders the current drug review process is unnecessarily opaque. Health Canada persists in maintaining a level of confidentiality that is inconsistent with public expectation and contributes to a public cynicism about the integrity of the process.<sup>195</sup>

The principles of good government require transparency and, through transparency, accountability. They also require a decision-maker that is free from bias. A closed process may give the appearance of a reasonable apprehension of bias, an allegation that is often leveled at Health Canada, which is seen as being too close to the drug companies.

## Inquiry Processes

### Introduction

Traditionally, the legal system requires a degree of certainty as to events that surround allegations of improper conduct, usually resulting in harm, in order for decision-makers to determine what, if any, punitive or compensatory mechanism should be used to ensure accountability, and what changes might be made to prevent future occurrences. Equally, the political system used in western democracies requires some mechanism to independently and transparently report upon events to determine what occurred, if and how similar events may be prevented, and to clarify appropriate accountabilities at the political level. In short, an inquiry is concerned about causation and prevention.<sup>196</sup> Accordingly, the mode of addressing contentious issues that arise is for an independent or quasi-independent individual or body to undertake an inquiry into the events to establish,

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<sup>194</sup> *Ibid.*

<sup>195</sup> Science Advisory Board Committee on the Drug Review Process, *Report to Health Canada* (Ottawa: Science Advisory Board Committee on the Drug Review Process, 2000).

<sup>196</sup> Allan Manson & David Mullen, "Introduction" in Allan Manson & David Mullen, eds., *Commissions of Inquiry: Praise or Reappraise* (Toronto: Irwin Law, 2003) 1 at 8 [Manson, "Introduction"].

usually, what happened, why it happened, if appropriate, how it could be prevented, and possible improvements in handling such issues in the future.

There are two primary modes of dealing with such inquiries that are common in most western countries, and certainly common in Canada. The first is to undertake an inquiry through the mechanism of a public inquiry. An individual or group of individuals is appointed with a precise mandate to undertake a public inquiry as an *ad hoc* response to some public event or issue. The second is the use of other investigative vehicles with an ongoing mandate to inquire into specific events and issues. Such processes would include statutory complaints processes (discussed in a separate section of this report), coroners' inquests, and other fatality inquiries.

Both public inquiries and coronial inquests and fatality inquiries have played a role in addressing issues related to patient safety within Canada, although arguably to a lesser extent than in some countries.<sup>197</sup> Most notable in this regard is the *Commission of Inquiry on the Blood System in Canada* (the Krever Commission)<sup>198</sup> which investigated at the federal level the contamination of the Canadian blood system with HIV and Hepatitis C and the *Report of the Manitoba Paediatric Cardiac Surgery Inquest: An Inquiry Into Twelve Deaths at the Winnipeg Health Sciences Centre in 1994*<sup>199</sup> (the Sinclair Report).

## Public Inquiries

Manson and Mullen suggest that the appropriate definition of a public inquiry is “all forms of inquiry directed to inquire into, and report on, the circumstances and causes of an event or series of events, or an issue of public importance, such as the inquiry into Canada’s health care system ... The common feature is whether the vehicle is intended to be an element in the development of public policy by uncovering facts and generating recommendations.”<sup>200</sup> Federal and provincial/territorial governments are empowered to call public inquiries and may also call joint public inquiries.

Public inquiries may be “policy review” inquiries that have a mandate to review major political, social or economic issues. Other public inquiries are “factual” inquiries which review a specific act or occurrence that has raised public concern. Lastly, many public

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<sup>197</sup> England and New Zealand in particular have made extensive use of public inquiry processes in respect of patient safety related events in the health system. Please refer to the country reports for further details.

<sup>198</sup> Canada, Commission of Inquiry on the Blood System in Canada, *Final Report: Commission of Inquiry on the Blood System in Canada* (Ottawa: Public Works and Government Services Canada, 1997) (Chair: Horace Krever).

<sup>199</sup> Manitoba, *The Report of the Manitoba Paediatric Cardiac Surgery Inquest: An Inquiry Into Twelve Deaths at the Winnipeg Health Sciences Centre in 1994* (Winnipeg: Provincial Court of Manitoba, 1998) (Associate Chief Judge Murray Sinclair), online: [Pediatric Cardiac Inquest <http://www.paediatriccardicinquest.mb.ca>](http://www.paediatriccardicinquest.mb.ca).

<sup>200</sup> Manson, “Introduction,” *supra* note 196 at 4.

inquiries function in both capacities providing both factual conclusions and extensive policy recommendations. The Krever Commission is a prime example.

There are a number of features common to all public inquiries in Canada:

- 1) authorization, powers, process and procedure are set out in legislation;
- 2) all inquiries are appointed by an Order in Council pursuant to powers granted to the Council by relevant legislation so public inquiries are discretionary appointments of the executive;
- 3) all inquiries are provided with a precise mandate;
- 4) all are semi-independent from government (government dictates the mandate, the budget, the commissioners and the duration of the process, but how the inquiry is conducted is a matter for the discretion of the Commissioner(s));
- 5) all provide advice to government and findings are not binding;
- 6) the proceedings almost always take place in public;<sup>201</sup>
- 7) the process culminates in a report to the Executive with recommendations which are almost always released publicly, either in whole or in part.

Public inquiries into patient safety related issues have been rare indeed in Canada. A more common mechanism used in relation to individual episodes of unsafe care is that of coronial inquests and fatality inquiries.

### **Coroners' Inquests and Fatality Inquiries**

Every province/territory in Canada has legislation that allows for coroners' inquests and fatality inquiries to investigate the cause of certain deaths. It is a program that provides checks and balances to ensure that 'suspicious' deaths are less likely to slip between the cracks. Unlike public inquiries, the legislation that governs the coronial process grants very little or no discretion as to in what circumstances a coroner must conduct an inquiry. The requirements in relation to what types of deaths must be reported and investigated are set out in legislation and differ from province to province. All provinces require investigations of deaths that occurred unexpectedly and most require investigations of deaths that are thought to have occurred as the result of negligence or which occur during pregnancy, or during or subsequent to anesthesia, or upon admission to hospital, although the parameters often differ.

For example, section 10(2) in Alberta, the *Fatality Inquiries Act*<sup>202</sup> states:

Deaths that occur under any of the following circumstances require notification under subsection (1):

- (a) deaths that occur unexplainedly;

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<sup>201</sup> The Arar Inquiry dealing with national security is an obvious exception.

<sup>202</sup> *Fatality Inquiries Act*, R.S.A. 2000, c. F-9.

- (b) deaths that occur unexpectedly when the deceased was in apparent good health;
- ...
- (d) maternal deaths that occur during or following pregnancy and that might reasonably be related to pregnancy;
- (e) deaths that may have occurred as the result of improper or negligent treatment by any person;
- (f) deaths that occur
  - (i) during an operative procedure,
  - (ii) within 10 days after an operative procedure,
  - (iii) while under anesthesia, or
  - (iv) any time after anesthesia and that may reasonably be attributed to that anesthesia.

Section 7(9) of the *Fatal Inquiries Act*<sup>203</sup> in Manitoba states that an inquiry will be made when:

- (a) the deceased person died
- ...
- (ii) by an act of suicide, negligence or homicide,
- (iii) in an unexpected or unexplained manner,
- ...
- (vi) suddenly of unknown cause,
- (vii) during a pregnancy or during recovery from a pregnancy,
- (viii) while under anesthesia or while recovering from an anesthesia or within 10 days of a surgical operation performed upon the person,
- ...
- (xi) within 24 hours of admission of the person to a hospital
- ...

Many provinces also have reporting requirements requiring witnesses to report deaths relating to negligence to the coroner/medical examiner, the police, or investigators.

Coroners also have little discretion in the conduct of their inquiry, most coronial investigations being limited to answering a variant of five key questions:

- the identity of the deceased
- how the deceased died
- when the deceased died
- where the deceased died
- by what means and in what circumstances the deceased died

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<sup>203</sup> *Fatal Inquiries Act*, C.C.S.M. 1990 c. F52.

Inquests are conducted in public but investigations in private. Reports are available as a result of information requests but do not appear to be available on publicly accessible databases.

In all provinces, coroners/medical examiners may make general recommendations aimed at preventing future deaths. For example, section 20 of the *Fatal Inquiries Act*<sup>204</sup> in Manitoba states:

Where, in the opinion of the chief medical examiner, a death might have been prevented if precautions had been taken or preventive measures had been in place, the chief medical examiner may make recommendations to the minister, to departments and agencies of government or to other persons as to possible precautions or preventive measures.

The coronial/medical examiner system is set up to investigate deaths that may have occurred as the result of negligence and to provide general recommendations to prevent such deaths. This system could be a valuable educative tool for patient safety improvements, as well as allowing some accountability and transparency about events.

## **Strengths and Weaknesses**

### ***Public Inquiries***

There have been many public inquiries conducted in Canada, although very few have related to patient safety. The most notable strength of a public inquiry process is its public and open nature. It may provide a forum for the public to receive information and to increase their awareness of important issues. Thus it serves the important role of increasing transparency and may also increase accountability, although this last is questioned by many critics, who note that public inquiry processes are sometimes used by government as a tool to ‘bury’ issues, hoping that the issue fades from public consciousness as the process unfolds.<sup>205</sup>

Accountability has other dimensions. Accountability involves persons who make public or quasi public decisions reporting, explaining and answering publicly for events. It involves government responding to the legislature and government leaders being answerable to the public about past and future actions in relation to the issue in question. Public inquiries foster this process.

Public inquiries also serve a valuable purpose in that the transparency of the process and outcome and the awareness of recommendations and subsequent action on these

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<sup>204</sup> *Ibid.*

<sup>205</sup> See Allan Manson & David Mullen, eds., *Commissions of Inquiry: Praise or Reappraise* (Toronto: Irwin Law, 2003) [Manson, *Commissions*].

recommendations may restore trust. Justice Cory summed up this view most succinctly when he stated:

Both the status and high public respect for the commissioner and the open and public nature of the hearing help to restore public confidence not only in the institution or situation investigated but also in the process of government as a whole.<sup>206</sup>

Public inquiries can also be a means to trigger reforms. If acted upon, substantive recommendations about policy and practice can substantially, or more incrementally, influence or result in changes to policy and/or service delivery. In the patient safety context, this was certainly the experience in the U.K. as the result of the Bristol<sup>207</sup> and Shipman<sup>208</sup> inquiries. In respect of the Krever Commission, however, it is suggested that recommendations were less influential because of the length of time it took to complete the report. This led to government(s) making substantive policy changes before the report was issued and a reluctance to alter these changes in light of the reforms suggested by Krever.<sup>209</sup> Thus recommendations for reform may or may not actually lead to a measurable subsequent improvement in outcomes at the interface between patient and healthcare provider. Hastily considered or implemented recommendations may, according to the law of unintended consequences, create further problems. However, they may also result in more carefully considered and focused strategies to create structures to address unsafe care in health systems.

Another strength of the public inquiry process is that inquiries can examine specific incidents of alleged malfeasance and the broader structural issues that surround those actions. This is in contrast with traditional legal mechanisms that abstract actions from their broader context and which attract criticism for the assumption that an act always has an identifiable author rather than being the product of a complex process or the activity of an organization.<sup>210</sup>

One weakness is certainly cost. The Krever Commission spent \$17.5 million. Public inquiries may not be a cost-effective mechanism to initiate policy change, but that would depend to a great extent upon the accomplishments of the inquiry in respect of the degree of policy change and whether this change has a significant effect on public awareness,

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<sup>206</sup> *Phillips v. Nova Scotia (Commission of Inquiry into the Westray Mine Tragedy)*, [1995] 2 S.C.R. 97 at 137.

<sup>207</sup> 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/>>.

<sup>208</sup> U.K., 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/>>.

<sup>209</sup> See Manson, *Commissions*, *supra* note 205.

<sup>210</sup> M. Trebilcock & L. Austin, "The Limits of the Full-Court Press: Of Blood and Mergers" (1998) 48 U.T.L.J. 1 at 8; Robert Centa & Patrick Macklem, "Securing Accountability Through Commissions of Inquiry: A Role for the Law Commission of Canada" in Allan Manson & David Mullen, eds., *Commissions of Inquiry: Praise or Reappraise* (Toronto: Irwin Law, 2003) 79 at 80; P. Robardet, "Should We Abandon the Adversarial Model in Favour of the Inquisitorial Model in Commissions of Inquiry" in P. Pross, I. Christie & J. Yogis, eds., *Commissions of Inquiry* (Toronto: Carswell, 1990) at 125.

outcomes, equity, transparency and accountability. Public inquiries are also lengthy processes. The Krever report, again, was directed to report within twelve months but took four years to deliver. This has also been the experience with public inquiries in respect of patient safety undertaken in other countries.

### *Coronial Inquests and Fatality Inquiries*

The coronial/medical examiner system is set up to investigate deaths that may have occurred as a result of negligence and to provide general recommendations to prevent such deaths. Therefore it could be a valuable educative tool for patient safety improvements, as well as allowing some accountability and transparency about events. It is an independent process, and may aid in restoring trust if the public is confident that investigations are rigorous and recommendations followed.

Transparency of inquests is high as the process is public; however, the more common investigations are less public and therefore less transparent. Reports are available, but only on request.

There does not appear to be any public database or repository or any tracking system, similar to the adverse events reporting systems and databases, either at the provincial or national level to establish patterns. This is an issue that is noted with concern in the U.S.<sup>211</sup> and is the subject of remedial action in the United Kingdom.<sup>212</sup> Even if there were such a system, variability in the statutory criteria for coronial review, 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 would cause difficulty in establishing such a register.

Although coroners/medical examiners have broad recommendatory powers, recommendations can be readily ignored depending upon the circumstances of the case. A high profile case may have sufficient visibility to compel compliance, as visibility enhances accountability. However, even when recommendations of import are made, the provincial model that underpins the coroner/medical examiner system means that recommendations are not readily shared across provincial boundaries. An example is the recommendations of the Sinclair report, which only saw substantial uptake in Manitoba, despite broad distribution.<sup>213</sup> Incidents which receive lesser publicity are even less likely to be broadly shared across the provinces.

The scope of the recommendations may also be limited due to the circumscribed nature of the investigation process, which must focus on answering five questions. Coroner/medical examiner reports may not have the authority or the resources to examine systemic issues beyond a narrow scope.

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<sup>211</sup> See country report in Appendix two.

<sup>212</sup> See country report in Appendix two.

<sup>213</sup> Jan Davies, "Painful Inquiry: Lessons from Winnipeg" (2001) 165 C.M.A.J. 1503.

## Compensation Systems

### Fault-based systems

A general legal and ethical principle in Western societies is that someone or something must be responsible for providing support and assistance to persons harmed through no fault of their own. In a number of common law countries, this responsibility and accountability is devolved to the individual(s) who caused the harm. The state provides a minimal social security safety net for those who suffer harm in cases where individual fault cannot be attributed. The Canadian legal system is based on the common law tradition, except in the province of Quebec which is governed by a *Civil Code*. In both legal systems, however, fault is the basis at law for determining whether health care injuries are compensable (except for vaccination injuries in Quebec for which there is a statutory no-fault system). In both the common law and civil law systems, patients are compensated for health care injuries only if they are able to prove on a balance of probabilities that their injuries resulted from the negligence of a health care provider. Injuries not attributable to negligence but to errors of judgment or unavoidable accidents are not compensable.

The premise behind fault-based systems is that when one person, due to his or her fault, injures another, there is a moral responsibility on the wrongdoer to restore the innocent victim to the position in which he or she was in before the wrongful act was committed and loss was caused.<sup>214</sup> In short, individuals must be responsible and be held accountable for actions or omissions that cause harm to others. The fault system is justified on the basis that it provides a variety of important functions in the field of health care. It is said to provide compensation, punishment, deterrence, appeasement, vindication, and education.<sup>215</sup>

### *Punishment, Deterrence, Appeasement and Vindication, and Education*

The theory is when the fault system awards damages it imposes a punishment for unacceptable conduct. It also provides specific and general deterrence because the defendant and his/her colleagues will not act in the same manner again. It is argued that the legally imposed duty of care is instrumental in maintaining safety standards.<sup>216</sup> It

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<sup>214</sup> Lewis Klar, "Tort and No-Fault" (1997) 5:3 Health L. Rev. 2 at 2.

<sup>215</sup> P.H. Osborne, "Compensation for Medical Injuries: An Uncertain Future" in Barney Sneiderman, John C. Irvine & Philip H. Osborne, eds., *Canadian Medical Law*, 3<sup>rd</sup> ed. (Toronto: Carswell, 2003) at 185 [Osborne].

<sup>216</sup> *Ibid.* at 191.

provides the plaintiffs a forum to obtain information about their condition and treatment, hold a health provider to account for his/her actions, and serves as a release valve for the plaintiff's anger, pain and bitterness.<sup>217</sup> Lastly, it is suggested that tort law instructs health care providers in the professional standards to which they are held accountable, and may result in changes to practice. For example, the extensive case-law surrounding informed consent has resulted in significant changes to the practice of all health providers.<sup>218</sup>

### ***Compensation***

In cases where fault is proven, compensation includes, but is not limited to, recovery for pain and suffering, replacement of loss of past and future income, costs of future care, gross-up for income tax and pre-judgment interest. Lawsuits by patients to establish fault against physicians and hospitals are notoriously “costly, slow and complex.”<sup>219</sup> In 2004, for example, 104 legal actions proceeded to trial against physicians. In 18 cases, the patient was successful; in 86 cases the physician was successful.<sup>220</sup> In 2004, there were 478 claims against 66,477 physicians paid by way of settlement or court order. The average damages award per claim paid was \$272,385.<sup>221</sup> Compensation awarded by Canadian courts to injured persons is more moderate than compensation awarded by courts in the United States. The differential may be attributed in part to a judicial initiative in 1978 capping the amount to be awarded for pain and suffering,<sup>222</sup> as well as general judicial conservatism in Canada.

### **No-Fault Systems**

Québec's no fault-system for vaccinations was enacted in 1985<sup>223</sup> after the failure of the *Lapierre* case<sup>224</sup> and in response to the general failure of the tort system to compensate

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<sup>217</sup> *Ibid.* at 191.

<sup>218</sup> *Ibid.* at 191.

<sup>219</sup> Ellen Picard & Gerald Robertson, “The Future” in Ellen Picard & Gerald Robertson, eds., *Legal Liability of Doctors and Hospitals in Canada*, 3<sup>rd</sup> ed. (Toronto: Carswell, 1996) 429.

<sup>220</sup> *Ibid.*

<sup>221</sup> Canadian Medical Protective Association, *2004 Annual Report* (Ottawa: C.M.P.A., 2005) [C.M.P.A., *Report*].

<sup>222</sup> *Andrews v. Grand and Toy Alberta Ltd*, [1978] 2 S.C.R. 229.

<sup>223</sup> *Public Health Act*, R.S.Q. c. S-2.2, ss. 70-78; *Regulation Under the Public Health Act*, R.R.Q. 2003, c. S-2.2, r. 1.

<sup>224</sup> A four-year-old girl contracted viral encephalitis after a measles vaccination and was left permanently disabled. The lower Court granted the child damages based on the no-fault liability of the State, Section 1057 of the *Civil Code*. However, the Québec Court of Appeal reversed this decision and the Supreme Court of Canada similarly rejected arguments advocating strict liability of the government for her injuries. *Lapierre v. P.G. du Québec*, [1985] 1 SCR 241.

those who experienced adverse events after vaccinations.<sup>225</sup> It provides compensation for those who can establish that they suffered harm from a vaccination. It is based upon the no-fault principles of the Québec auto insurance scheme. The scheme is overseen at the provincial level and ‘piggybacks’ upon the already established auto insurance scheme. No fault is required to be established, merely that the harm be causally linked to the vaccine on the balance of probabilities.

### **Policy Reports and Statements**

Two reports of note that specifically address liability and compensation for health care injuries (adverse events) in Canada are the Pritchard Report<sup>226</sup> of 1990 and, more recently, a CMPA Report<sup>227</sup> of 2005.

#### ***Pritchard Report***

The Pritchard Report found that between 1971 and 1987 there was an increase in Canada in the number of claims filed against and paid by physicians and health care institutions.<sup>228</sup> Despite this, less than ten percent of persons with viable claims for health care injuries received compensation.<sup>229</sup> The Report identified the threat of medical malpractice actions as an important mechanism for reducing the frequency of health care injuries,<sup>230</sup> more so than the disciplinary processes of the medical profession.<sup>231</sup> Pritchard concluded therefore that the existing fault-based tort system in Canada should not be completely replaced with a no-fault system. Noting also, however, that a greater portion of patients suffering from serious health care injuries (those experiencing permanent partial disability or loss of capacity for at least eight weeks) ought to be compensated for their injuries, the Report recommended that a no-fault system be made available for these patients. In this alternate no-fault system (where, if elected, action in tort would be foreclosed), compensation would be limited to costs of rehabilitation, replacement of past and future lost income, and future health and home care costs not covered by provincial health insurance plans.<sup>232</sup> The Report also recommended other reforms to enhance health care safety such as mandatory quality assurance, risk

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<sup>225</sup> Nicole Kutlea, “The Case for a Vaccine Related Injury Compensation Scheme in Canada,” online: University of Toronto Law <[www.law.utoronto.ca/documents/zhealthlaw04/kutlesa\\_handout.doc](http://www.law.utoronto.ca/documents/zhealthlaw04/kutlesa_handout.doc)> [Kutlea].

<sup>226</sup> J. Robert S. Pritchard, *Liability and Comprehension in Health Care* (Toronto: University of Toronto Press, 1990) [Pritchard].

<sup>227</sup> Canadian Medical Protective Association, *Medical Liability Practices in Canada: Towards the Right Balance* (Ottawa: C.M.P.A., 2005) [C.M.P.A., *Balance*].

<sup>228</sup> Pritchard, *supra* note 226 at 15-16.

<sup>229</sup> *Ibid.* at 17.

<sup>230</sup> *Ibid.* at 6.

<sup>231</sup> *Ibid.* at 19.

<sup>232</sup> *Ibid.* at 29.

management, peer review programmes for accreditation of health care institutions<sup>233</sup> and expanding the range of health care institutions subject to accreditation.<sup>234</sup>

Eight years later, Pritchard reflected on what had happened since his report in 1990 as follows: “In summary, I would say not much. . . . Most of what we recommended has not been done.”<sup>235</sup>

### ***CMPA Report***

In a 2005 report,<sup>236</sup> the C.M.P.A. re-affirmed the recommendations of the Pritchard Report that the existing tort-based system for compensating most health care injuries should be retained.<sup>237</sup> While it rejected Pritchard’s recommendations of a no-fault system for patients suffering serious healthcare injury, C.M.P.A. did suggest changes to the existing system, including a segregated compensation system for birth-related neurological injuries. According to C.M.P.A., a large part of the organization’s reserves are set aside for these cases which are very expensive when there is a finding of liability.<sup>238</sup>

Another change advocated by the C.M.P.A. was in the area of information reporting. In this regard, it recommended that legislation be passed requiring that all information on adverse events be fully reported and analyzed for purposes of improving patient safety. At the same time, the legislation should protect information collected for this purpose from the processes used to determine patient compensation and physician accountability (for those processes the information should continue to be guided by existing legal rules). Implementation of this recommendation would in effect introduce a “firewall” between information generated for different purposes.<sup>239</sup> The result, according to C.M.P.A., would facilitate learning from avoidable and unavoidable adverse events in order to prevent recurrence on the one hand, while preserving due process in relation to fault and professional accountability for avoidable adverse events (deterrence) on the other hand.

### ***Other***

There have been calls by the judiciary for reforms to the system of compensating individuals for harm occurring as the result of receiving health services. Justice Krever, in *Ferguson v Hamilton Civic Hospitals*,<sup>240</sup> echoed calls by Justice Linden in *Davidson v Connaught Laboratories et al*,<sup>241</sup> when he wrote:

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<sup>233</sup> *Ibid.* at 32.

<sup>234</sup> *Ibid.*

<sup>235</sup> Health Canada, online < [http://www.hc-sc.gc.ca/english/care/report/3\\_legal.html](http://www.hc-sc.gc.ca/english/care/report/3_legal.html)>.

<sup>236</sup> C.M.P.A., *Balance*, *supra* note 227.

<sup>237</sup> *Ibid.* at 5.

<sup>238</sup> C.M.P.A., *Report*, *supra* note 221.

<sup>239</sup> *Ibid.* at 19.

<sup>240</sup> *Ferguson v. Hamilton Civic Hospitals et al* (1983), 40 O.R. (2d) 577 (H.C) at 618-19 [*Ferguson*].

<sup>241</sup> *Davidson v. Connaught Laboratories et al.* (1980), 14 C.C.L.T. 251.

I confess to a feeling of discomfort over a state of affairs, in an enlightened and compassionate society, in which a patient, who undergoes a necessary procedure and who cannot afford to bear the entire loss, through no fault of his and reposing full confidence in our system of medical care, suffers catastrophic disability but is not entitled to be compensated because of the absence of fault on the part of those involved in his care. While it may be that there is no remedy for this unfortunate and brave plaintiff and that this shortcoming should not be corrected judicially, there is in my view, an urgent need for correction.

His view was subsequently supported by the Ontario Court of Appeal.<sup>242</sup>

### **Strengths and Weaknesses**

A strength of the existing tort-based system can be found in the fact that when patients are able to prove fault, they are fully compensated for their losses. A related weakness of the system is the difficulty and expense of proving fault, with the result that many legitimate claimants are not compensated at all. Further issues of equity are raised by the numbers of potential plaintiffs who do not make a claim and those who are not aware that they could make a claim because they have not been informed that the treatment or care provided to them was possibly negligent. The current fault-based system therefore raises significant equity issues. Arguably as significant is the inequitable treatment of those who suffered an adverse event that was not due to negligence but who have no avenues to seek redress, unless they have suffered a vaccination injury in Québec.

Two significant claims made for the fault-based model are that it is an effective deterrence mechanism for the health provider being sued and other health providers and is an important educative tool. The evidence to support these claims is decidedly mixed. Some point to the Canadian case of *Anderson v Chasney*<sup>243</sup> and suggest that it caused subsequent changes in practice in Canada in respect of using sponges with tapes and counting sponges during surgery.<sup>244</sup> However, there is also some doubt about the ability of tort law to affect practice. In Canada, a 1984 survey of physicians suggested little uptake of the doctrine of informed consent subsequent to the Supreme Court decision in *Reibl v Hughes* in 1980.<sup>245</sup> A recent U.S. meta-analysis of the evidence found some evidence of deterrence but concluded that overall the evidence was thin.<sup>246</sup> Some studies also suggest that if tort law influences the behaviour of health providers, it may do so in less desirable ways by pushing them towards defensive medicine with its associated costs

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<sup>242</sup> *Ferguson, supra* note 240 at 755, MacKinnon A.C.J.

<sup>243</sup> 57 Man. R. 343, [1949] 4 D.L.R. 71 (C.A.), aff'g [1950] 4 D.L.R. 223 (S.C.C.).

<sup>244</sup> Osborne, *supra* note 215 at 192.

<sup>245</sup> Gerald Robertson, "Informed Consent in Canada: An Empirical Study" (1984) 22 Osgoode Hall L.J. 139-161; reprinted (1985) 18 Annals of the Royal College of Physicians & Surgeons of Canada 49 at 49-53, 125-130. This was within four years of the ruling so this may only demonstrate that the pace of change was slow. Most would agree that informed consent is an established facet of good medical practice today.

<sup>246</sup> M. Mello & T Brennan, "Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform" (2002) 80 Texas L. Rev. 1595.

and tests and treatments that may be of no or marginal benefit, although again this correlation is weak.<sup>247</sup>

The mechanism used to ensure deterrence under the fault-based model may also be weaker than it appears. Punitive damages are usually paid by an insurance plan rather than an individual or institution and, except in rare cases, are rarely risk adjusted on an individual basis; thus the health provider does not experience any financial loss.

From a patient safety perspective, the aims of the systems-centered patient safety movement (discussed in Appendix 1) are directly at odds with the underlying premise of the fault-based system of liability for negligent acts. Supporters of a fault-based system believe that the threat of litigation makes health providers practice more safely because they are deeply concerned about the possibility of blame and punitive measures being taken against them. The patient safety movement is committed to the creation of non-punitive systems that rarely allocate blame, focus on systems rather than individuals, recognize the complexities of modern healthcare practice, and encourage communication, cooperation and learning. Transparency is a key value of the patient safety movement and of good governance more generally. The patient safety movement argues that fault-based systems inhibit transparency because the systems do not create an environment that is conducive to the open discussion and learning from mistakes; rather, fear of litigation is such that mistakes are not acknowledged, let alone discussed. Even supporters of fault-based systems agree that this is so and urge further informational protections to allow open dialogues about error.<sup>248</sup> The processes associated with litigation also can act to limit public disclosure of information. Every claim that is settled does not provide a learning opportunity for health providers and does not allow public accountability.

The efficiency of the fault-based system versus the no-fault system is highly contested. Some suggest that no-fault is more efficient in that its traditional model involves one agency with defined procedures and thus there are significant efficiency costs, even though the numbers of persons receiving coverage substantially increase, resulting in costs that are similar to or less than the current system.<sup>249</sup> Others argue the opposite.<sup>250</sup>

The Québec no fault system for vaccines is an efficient and relatively uncomplicated model, but is problematic in that the causation barrier is high so there is a limited success rate for applicants to the scheme.<sup>251</sup>

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<sup>247</sup> L. Dubay, R. Kaestner & T Waidman, "The Impact of Malpractice Fears on Caesarian Section Rates" (1999) 18 J. Health Econ. 491; A. Localio *et al.*, "Relationships between Malpractice Claims and Caesarian Delivery" (1993) 269 J.A.M.A. 366; D. Kessler & M. McClellan, "Do Doctors Practice Defensive Medicine?" (1996) 111 Q. J. Econ. 353; *Ibid.*

<sup>248</sup> C.M.P.A., *Balance*, *supra* note 227.

<sup>249</sup> See *e.g.*, David Studdert & Troyen Brennan, "No-Fault Compensation for Medical Injuries: The Prospect of Error Prevention" (2001) 286 J.A.M.A 217.

<sup>250</sup> See *e.g.*, C.M.P.A., *Balance*, *supra* note 227. The company commissioned by the CMPA to undertake this analysis suggests that in Canada the adoption of a no-fault plan would see costs rise from \$225 million to approximately \$40 billion. Even the application of "filters" requiring injuries to be "unintended and avoidable" could see annual system costs rise to \$2.6 billion.

<sup>251</sup> Kutlea, *supra* note 225.

## Other Patient Complaint Mechanisms

The rise of the consumer movement in the 1970s led to demands for mechanisms through which consumers of health services could express dissatisfaction without resorting to the traditional processes that were available. In addition to the statutory complaints processes for patient complaints about regulated health professionals and civil litigation, legislated complaints mechanisms exist for patients concerned about the care received in health facilities exist in Quebec and Alberta. Internal complaints processes are also maintained voluntarily in a number of Canadian health care institutions and regions.<sup>252</sup>

### Complaints Mechanisms

In Alberta, the Health Facilities Review Committee is responsible for investigating patient complaints concerning “the care and treatment and standards of accommodation received by that patient or any other patient in the hospital.”<sup>253</sup> Under the *Health Facilities Review Act*, the definition of “hospital” includes all approved nursing homes, mental health hospitals and acute and auxiliary care hospitals.<sup>254</sup> The Committee also conducts routine inspections of health care facilities as part of its legislative mandate.<sup>255</sup> The 12 member Committee is chaired by members of Alberta’s Legislative Assembly, while the other members are chosen by the Minister of Health and Wellness from the general public to represent health care consumers.<sup>256</sup> Patients are encouraged to take their concerns to the staff, institution or regional health authority involved before filing a complaint with the Committee. Received complaints are reviewed by the Committee to ensure they are within its mandate. The Committee does not investigate complaints about a health professional’s conduct or patient abuse, which must be reported to separate authorities. Complaints must be in relation to a specific patient and can be about “any aspect of patient/resident care, safety or satisfaction,” such as medication administration, the use of restraints or food quality.<sup>257</sup> Accepted complaints are investigated by a team of committee members. The *Act* gives the Committee the right to enter a facility and review hospital records as part of an investigation, but the Committee cannot compel witnesses to be interviewed.<sup>258</sup> Using information gathered from documentation, interviews and committee observations made at the facility, the Committee prepares a written report of its findings and any recommendations, which is then forwarded to the

<sup>252</sup> Flood, *supra* note 133 at 529.

<sup>253</sup> *Health Facilities Review Act*, R.S.A. 2000, c. H-3, s. 8. The *Act* was proclaimed in 1978.

<sup>254</sup> *Ibid.* at s. 1(b); Alberta Health Facilities Review Committee, online: Government of Alberta <<http://www.health.gov.ab.ca/about/HFRC/index.html>>[Alberta Health Facilities Review Committee].

<sup>255</sup> *Health Facilities Review Act*, *ibid.* at s. 7.

<sup>256</sup> Public members are not employees of the government and serve on a part-time basis. Alberta Health Facilities Review Committee, *supra* note 254.

<sup>257</sup> *Ibid.*

<sup>258</sup> *Health Facilities Review Act*, *supra* note 253 at ss. 9-10. The committee cannot obtain financial records and cannot access records with individually identifying information unless the patient consents.

complainant, the administrator and owner of the facility, the CEO of the regional health authority and the Minister of Health and Wellness. Regional health authorities and facilities are asked to respond in writing to the Committee's recommendations, which the Committee reviews in its monthly meetings. While the Committee cannot require facilities to implement its recommendations, it can make unannounced inspections of facilities. The Committee has indicated that voluntary compliance with its recommendations is high.<sup>259</sup> The Committee is required to submit an annual report to the Minister, who must present it to the Legislative Assembly.<sup>260</sup>

Alberta has also passed, but not yet proclaimed in full, the *Ombudsman Amendment Act 2003*.<sup>261</sup> Section 5 states:

Patient concerns resolution process

12.1(1) In this section, “patient concerns resolution process” means a patient concerns resolution process of a health authority established in accordance with regulations governing that health authority.

(2) It is the function and duty of the Ombudsman to investigate any decision or recommendation made, or any act done or omitted, relating to a patient concerns resolution process and affecting any person in the person's personal capacity, in or by

- (a) a health authority, or
- (b) an officer, employee or member of a health authority or a person engaged by a health authority in the exercise of any power or the performance of any function conferred on the officer, employee, member or person relating to the patient concerns resolution process.

(3) The Ombudsman may make an investigation relating to a patient concerns resolution process

- (a) on a complaint made to the Ombudsman by any person affected by a decision, recommendation, act or omission referred to in subsection (2), or
- (b) on the Ombudsman's own motion.

Legislation in Quebec sets out a two-tiered complaints examination system.<sup>262</sup> The system allows patients to lodge a complaint about the health services they received, ought to have received, are receiving, or require while in the care of public institutions or

<sup>259</sup> Alberta Health Facilities Review Committee, *supra* note 254.

<sup>260</sup> *Health Facilities Review Act*, *supra* note 253 at s. 16.

<sup>261</sup> *Ombudsman Amendment Act*, S.A. 2003, c. 30.

<sup>262</sup> *An Act respecting the Health and Social Services Ombudsman*, R.S.Q. c. P-31.1 [*Ombudsman*]; *Health Services and Social Services Act*, *supra* note 41. The first complaints examination system in place in 1993 had three levels, institutional, regional and a final level consisting of a Complaints Commissioner. The current simplified system was implemented through *An Act respecting the Health and Social Services Ombudsman*, which came into effect on April 1<sup>st</sup>, 2002. See Protecteur des usagers en matiere de sante et de services sociaux, “Brief History,” online: <<http://www.protecteurdesusagers.gouv.qc.ca/fr/>>.

institutions receiving government grants.<sup>263</sup> The system is also designed to enforce the legal rights of patients. The *Act Respecting Health and Social Services* gives users of health services a number of rights, including the right to receive “scientifically, humanly and socially appropriate” health services “with continuity and in a personalized and safe manner.”<sup>264</sup> The first tier in the system involves addressing a complaint to an institution or regional agency, which must have in place a complaint examination procedure that meets legislative requirements and a local or regional service quality commissioner.<sup>265</sup> Commissioners are responsible for diligently examining patient complaints and enforcing the rights of patients.<sup>266</sup> Complaints concerning a physician, resident, dentist or pharmacist are addressed by a separate process.<sup>267</sup> Boards of directors are required to take measures to preserve at all times the independence of commissioners.<sup>268</sup> Subject to certain confidentiality exceptions, all documentation and information, including information contained in a patient’s record, required by commissioners during an investigation must be provided to them and individuals must attend meetings called by a commissioner unless they have a valid reason.<sup>269</sup> Once commissioners have received a complaint, they have 45 days to investigate the complaint and give a written response, including their reasoning and recommendations, to the complainant and the appropriate authority within the institution or regional agency (referred to in the legislation as a “regional board”).<sup>270</sup> They also must inform complainants about the process for applying to the second and final tier of the system, the Health and Social Services Ombudsman (“Health Services Ombudsman”). The Minister of Health and Social Services receives an annual report from regional agencies, who in turn receive reports from institutions, concerning the complaints process.<sup>271</sup> Included in these reports are the most significant actions recommended by local and regional commissioners to improve user satisfaction, the quality of health services, and the enforcement of patient rights.<sup>272</sup> The reports must be tabled in the National Assembly and sent to the Health Services Ombudsman.

The Health Services Ombudsman’s functions within the system include:

- ensuring patients are respected and their rights are enforced;

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<sup>263</sup> *Health Services and Social Services Act*, *supra* note 41 at ss. 34, 95; Protecteur des usagers en matiere de sante et de services sociaux, “About Which services Can complaints Be Filed?,” online: <<http://www.protecteurdesusagers.gouv.qc.ca/fr/>> [Protecteur, “About”]

<sup>264</sup> *Health Services and Social Services Act*, *ibid.* at ss. 5, 13 stipulates that this right is not freestanding, but its exercise is limited by “the human, material, and financial resources” of institutions.

<sup>265</sup> *Ibid.* at ss. 62-63.

<sup>266</sup> *Ibid.* at s. 66.

<sup>267</sup> *Health Services and Social Services Act*, *supra* note 41 at ss. 42, 45, 51-52. A medical examiner appointed by the board of directors of an institution is responsible for examining these complaints. The medical examiner’s handling of a complaint is subject to re-examination by a review committee.

<sup>268</sup> *Health Services and Social Services Act*, *supra* note 41 at s. 64.

<sup>269</sup> *Health Services and Social Services Act*, *supra* note 41 at ss. 19, 36, 69.

<sup>270</sup> *Health Services and Social Services Act*, *supra* note 41 at ss. 33(6), 66(6); Protecteur, “About,” *supra* note 263.

<sup>271</sup> *Health Services and Social Services Act*, *supra* note 41 at ss. 76.10-76.14.

<sup>272</sup> *Health Services and Social Services Act*, *supra* note 41 at ss. 5, 76.12. They also contain a summary of all reports received from institutions, including information about complaints concerning physicians, dentists and pharmacists.

- examining complaints when the patient disagrees with a commissioner's conclusions, a commissioner fails to meet the 45 day time limit, or the patient is dissatisfied with the response of the institution or regional agency to a commissioner's recommendations;
- ensuring the complaint examination procedures of institutions and regional agencies comply with legislative requirements in the *Act Respecting Health and Social Services*;
- intervening on his or her own initiative should the Ombudsman have reasonable grounds<sup>273</sup> to believe that the acts or omissions of institutions, regional agencies or individuals practicing on their behalf will adversely affect the rights of patients;
- advising the Minister on issues such as the enforcement of patient rights and improving the quality of health and social services.<sup>274</sup>

The Health Services Ombudsman is required to establish a complaints examination procedure. The procedure must stipulate, for example, that complaints are to be made in writing and both the complainant and the institution or regional agency are allowed to present their observations.<sup>275</sup> The Health Services Ombudsman, as well as commissioners, can dismiss complaints that are frivolous, vexatious or made in bad faith.<sup>276</sup> The Health Services Ombudsman also has a similar ability to access information as a commissioner.<sup>277</sup> However, the Health Services Ombudsman may choose to hold an inquiry as part of the complaints examination process, and if so, the Ombudsman will gain the powers and immunities of a public inquiry commissioner.<sup>278</sup> A representative of the Health Services Ombudsman conducts the examination and the conclusions reached, as well as the reasoning behind them and any recommendations, must be communicated to the complainant and institution or regional agency involved. Within 30 days of receiving the Health Services Ombudsman's recommendations, the institution or regional agency must send a written report to the Health Services Ombudsman and the complainant detailing what actions have been taken in response to the recommendations or the reasons why it has decided not to act on them.<sup>279</sup> While the Health Services Ombudsman cannot order institutions or regional agencies to follow the recommendations, if the Ombudsman is not satisfied with the response of the institution or regional agency, he or she can write to the Minister. The Health Services Ombudsman is required by law to name in an annual report to the Minister any institution or regional

<sup>273</sup> *Ombudsman, supra* note 262 at s. 20. The grounds on which the Health Services Ombudsman can intervene are subject to certain legislated parameters. Intervention is only permissible when recourse to the complaints process at the institutional or regional level "would likely be compromised, serve no purpose or be illusory." Cases warranting intervention include those involving possible reprisals or especially vulnerable patients.

<sup>274</sup> *Ibid.* at ss. 7, 27.

<sup>275</sup> *Ibid.* at s. 10.

<sup>276</sup> *Ibid.* at s. 13. In addition, the Health Services Ombudsman may choose to refuse or cease dealing with complaints where if in his or her opinion, the Health Services Ombudsman's involvement would serve no purpose, if the length of time involved makes it impossible to examine the complaint, or if more than two years has passed between the complainant's receipt of the commissioner's conclusions.

<sup>277</sup> *Ibid.* at s. 14.

<sup>278</sup> *Ibid.* at s. 9. The Health Services Ombudsman would not have the power to order imprisonment.

<sup>279</sup> *Ibid.* at s. 15.

agency who decides not to adopt a recommendation for corrective action and is permitted to identify them publicly.<sup>280</sup> The Health Services Ombudsman reports that almost 90% of the entities involved accept the recommendations and inform the Ombudsman of steps planned to implement them.<sup>281</sup> Under Quebec's legislation, statements, information or documents provided as part of the examination process are not admissible as evidence in judicial proceedings or proceedings with adjudicative functions, user's complaint files are confidential, and reprisals against complainants are prohibited.<sup>282</sup>

### Strengths and Weaknesses

In a national survey conducted in 2002, nine out of ten Canadians indicated their support for an independent commissioner or ombudsperson with the power to hear complaints about health care providers and services and make recommendations.<sup>283</sup> While voluntary internal complaint mechanisms within healthcare institutions and regions are positive developments, patients may see them as "lacking independence and impartiality."<sup>284</sup> The advantages of the a traditional model are that they are more direct, and less expensive, cumbersome and time consuming. While no empirical studies appear to have been done on the effectiveness of Canadian patient complaints mechanisms as a means of improving patient safety, the legislative complaints mechanisms in Quebec and Alberta increase transparency and accountability within the system and provide an independent forum capable of addressing individual complaints and systemic issues that may arise from them. Both the Health Services Ombudsman and the Health Facilities Review Committee report high voluntary uptake of recommendations. Quebec's legislative framework provides consistency at the local level in that it requires a complaints procedure with mandatory elements to be in place in all public institutions and regional agencies and has an independent body, the Health Services Ombudsman, to monitor compliance. The system has mechanisms through which issues can be identified and reported to the Minister, as the Health Services Ombudsman may advise the Minister whenever necessary about the enforcement of patient rights and quality improvement and there is annual system wide reporting that keeps the Minister informed of the nature of complaints received and important recommendations. However, the complaints process applies only to public institutions and concerns have been raised that the Health Services Ombudsman's independence is somewhat compromised in that the position is answerable to the Minister rather than the National Assembly.<sup>285</sup>

<sup>280</sup> *Ibid.* at ss. 19, 27, 38. The Minister must also table the annual report in the National Assembly.

<sup>281</sup> Protecteur des usagers en matiere de sante et de services sociaux, "FAQ," online: <<http://www.protecteurdesusagers.gouv.qc.ca/fr/>>.

<sup>282</sup> *Ombudsman*, *supra* note 262 at ss. 29-37; *Health Services and Social Services Act*, *supra* note 41 at ss. 73-76.5.

<sup>283</sup> IBM Business Consulting Services, *Health Insider: Survey No. 8*, Fall/Winter 2002 (Toronto: IBM Consulting Services), as cited in C. Flood and T. Epps, "Waiting for Health Care: What Role for a Patients' Bill of Rights?" (2004) 49 McGill L.J. 515 at 519.

<sup>284</sup> Flood, *supra* note 133 at 529.

<sup>285</sup> *Ibid.* at 538.

## Adverse Event Reporting Systems

Adverse events reporting systems are a structural facet of safety regulation in other sectors, but they are a relatively recent innovation in the health system. In addition to Health Canada's national adverse reporting systems for health products discussed earlier, adverse event reporting systems exist at the provincial level.<sup>286</sup>

### Provincial Systems

Some provinces have used legislation to create a framework for province-wide adverse event reporting systems. With the passage of *The Regional Health Services Act* in 2002, Saskatchewan became the first province to put in place legislation requiring the mandatory reporting of adverse events to its health department. As of September 2004, when both section 58 of *The Regional Health Services Act* and *The Critical Incident Regulations* came into force, health care organizations (HCOs) and regional health authorities (RHAs) are required to give notice of critical incidents<sup>287</sup> arising from their operations within three business days, or as soon as possible thereafter. HCOs notify their RHA of critical incidents, while RHAs give notification of their critical incidents and those of their HCOs directly to the Department. After giving notification, RHAs and HCOs must investigate the critical incident and submit a written report. The report must include at a minimum a description of the circumstances surrounding the incident, any contributing factors that if modified may prevent the incident's reoccurrence, past actions and future steps to be taken by HCOs or RHAs as result of the investigation, and any other recommendations. Critical incidents that must be reported to the Department of Health are listed in the *Saskatchewan Critical Incident Reporting Guideline, 2004*.<sup>288</sup> Reportable incidents fall under following categories: surgical events, product or device events, patient protection events, care management events, environmental events and criminal events. A confidentiality provision in the regulations stipulates that notices and reports must not identify by name the patient, health care providers or any other individual who knows of the critical incident.<sup>289</sup> Notices and reports are not admissible as evidence in legal proceedings and witnesses cannot be asked to produce them, any information they contain, or any documentation used in their preparation.<sup>290</sup> Witnesses

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<sup>286</sup> At the institutional level, healthcare institutions may gather incident reports for review and track them as a matter of policy. The evidentiary protections afforded by provinces to these activities will be discussed separately.

<sup>287</sup> See Saskatchewan Health, *Saskatchewan Critical Incident Reporting Guideline, 2004*, at 1, online: Saskatchewan Health < [http://www.health.gov.sk.ca/mc\\_sk\\_ci\\_rep\\_guideline\\_2004.pdf](http://www.health.gov.sk.ca/mc_sk_ci_rep_guideline_2004.pdf) > where the term "critical incident" defined as a "serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function" relating health services provided by RHAs or HCOs.

<sup>288</sup> The guideline was adapted from the U.S., National Quality Forum, *Serious Reportable Events in Healthcare: A Consensus Report* (Washington: The National Quality Forum, 2002). The NQF is a private, non profit organization based in the United States.

<sup>289</sup> *The Critical Incident Regulations*, R.R.S. 2004, c. R-8.2, Reg. 3, s. 10.

<sup>290</sup> *The Regional Health Services Act*, S.S. 2002, c. R-8.2, ss. 58(5)-(6).

also cannot make a statement or be questioned about the investigation of a critical incident. These privileges do not apply to factual information about the critical incident contained in notices and reports and information prepared for “the purpose of providing care or treatment,” unless this information is fully recorded and available in another record.<sup>291</sup>

In Quebec, any person working in an institution providing health services is required by law to report accidents<sup>292</sup> or incidents<sup>293</sup> as soon as possible after becoming aware of them to the executive director of their institution or an individual designated by the executive director.<sup>294</sup> Reports, with names removed, must also be submitted to the regional board at agreed intervals or when required. Healthcare users also have the right to be informed as soon as possible of accidents that have actual or potential health consequences and any corrective or preventative measures taken.<sup>295</sup> Each institution is required to create a risk and quality management committee, which is charged with setting up a local register of accidents and incidents, analyzing their causes and recommending preventative measures to the institution’s board of directors.<sup>296</sup> A provision not yet in force would require the Minister of Health and Social Services to maintain a province-wide registry using information from local registries in order to monitor and analyze accidents and incidents and ensure preventative measures are taken.<sup>297</sup> These provisions form part of Bill 113.<sup>298</sup> Passed in December 2002, it contains a number of amendments to Quebec’s *Act Respecting Health Services and Social Services* aimed at improving the safety of health services delivery in the province. A 2004 survey showed that over 60 percent of healthcare facilities had established quality and risk management committees, 64 percent had a local registry and two thirds had solicited accreditation for their facility.<sup>299</sup>

Manitoba passed legislation in June 2005 containing mandatory critical incident reporting requirements, but the Act had not been proclaimed in force as of December 30, 2005.<sup>300</sup> Similarly to Saskatchewan, health corporations and prescribed health care organizations

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<sup>291</sup> *Ibid.* at s. 58(7).

<sup>292</sup> See *Health Services and Social Services Act*, *supra* note 41 at s. 8 where an accident is defined as “an action or situation where a risk event occurs which has or could have consequences for the state of health or welfare of the user, a personnel member, a professional involved or a third person.”

<sup>293</sup> *Ibid.* at s. 183.2 defines an incident as “means an action or situation that does not have consequences for the state of health or welfare of a user, a personnel member, a professional involved or a third person, but the outcome of which is unusual and could have had consequences under different circumstances.”

<sup>294</sup> *Ibid.* at s. 233.1.

<sup>295</sup> *Ibid.* at s. 8.

<sup>296</sup> *Ibid.* at s. 183.2. See Micheline Ste-Marie, “Patient Safety: Le Groupe Vigilance pour la Sécurité des Soins: A Québec Perspective” (2005) 8 Health Care Q. 119 at 120 where it is reported that an April 2004 survey of health care institutions indicated 64% had established a local registry [Ste-Marie].

<sup>297</sup> *An Act to Amend the Act Respecting Health Services and Social Services as Regards the Safe Provision of Health Services and Social Services*, R.S.Q. 2002, c. 71, s. 15.

<sup>298</sup> *Ibid.* at s. 10.

<sup>299</sup> Discussed in Ste-Marie, *supra* note 296 “Patient Safety: Le Groupe Vigilance pour la Sécurité des Soins: A Québec Perspective” (2005) 8 Spec. Healthcare Q. 119 at 119.

<sup>300</sup> *The Regional Health Authorities Amendment and Manitoba Evidence Amendment Act*, S.M. 2005, c. 24.

would notify their regional health authority of critical incidents<sup>301</sup> and the authority would notify the Minister of Health. The regional health authority would also notify the Minister directly of critical incidents arising from its operations, as would certain designated health care organizations. The Manitoba legislation would require health corporations, organizations, and the regional health authority to set up a critical incident review committee responsible for investigating the critical incident and preparing a written report of findings and recommendations. Reports and information would reach the Minister using the same process for notifications. Retaliation against those who provide information in order to meet the requirements of the Act is prohibited. Regional health authorities, health corporations and organizations would also have a duty to inform the individual patient of the facts of the incident, its known consequences for the patient, and actions taken or to be taken to address the consequences. A record of this information would have to be available free of charge to the patient. Notices, reports, and information prepared solely for the use of the review committee would not be accessible via the province's *Freedom of Information Act* or *Personal Health Information Act*, with certain exceptions.<sup>302</sup> The province's Evidence Act would be amended to privilege committee proceedings, so that witnesses could not be questioned regarding committee proceedings, and notices, reports and information prepared for or used solely by the committee would not be admissible.

### Strengths and Weaknesses

Effective reporting systems that subsequently identify, track and evaluate adverse events, near misses and critical incidents in order to create strategies to prevent or reduce their occurrence are arguably important tools for improving patient safety within the Canadian health care system. Reporting systems form a key plank of the patient safety movement's strategy to improve patient safety by fostering open learning environments. Adverse events reporting systems potentially can identify trends or patterns in adverse events and enable remedial action through awareness and education to prevent or minimize the likelihood of future adverse events of the same type. It has proved successful in other sectors in having a measurable improvement in safety since its introduction.<sup>303</sup>

A report issued by the National Steering Committee on Patient Safety in September 2002 noted that Canada is behind several other countries in developing tools for measuring adverse events and described existing mechanisms to identify them as incomplete.<sup>304</sup>

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<sup>301</sup> See *ibid.* at s. 53.1 where a critical incident is defined as "an unintended event that occurs when health services are provided to an individual and results in a consequence to him or her that (a) is serious and undesired, such as death, disability, injury or harm, unplanned admission to hospital or unusual extension of a hospital stay, and (b) does not result from the individual's underlying health condition or from a risk inherent in providing the health services."

<sup>302</sup> *Ibid.* at ss. 53.10(1)-(2). Exceptions include information in a record created for the purpose of providing health services to an individual and information that a facility or health care provider is required to create and maintain by law.

<sup>303</sup> See *e.g.* discussion in, Paul Barach & Stephan Small, "Reporting and Preventing Medical Mishaps: Lessons from Non-Medical Near Miss Reporting Systems" (2000) 320 *BMJ* 759 [Barach].

<sup>304</sup> National Steering Committee, *supra* note 21 at 15.

The report makes a number of recommendations related to improving the reporting of adverse events, incidents and near misses, including:

- the adoption of non-punitive reporting policies within a quality improvement framework across the system that encourage and reward reporting, with limited exceptions;
- the review and revision of legislation across all Canadian jurisdictions in order to protect patient safety data and reports from disclosure in legal proceedings.<sup>305</sup> Facts relating to the event should be recorded on the patient's health record and should not be privileged. De-identified information could be entered into a provincial or national database to facilitate the sharing of lessons learned across jurisdictions (see the Rules of Evidence section of this report).
- the review and piloting of reporting and surveillance systems to determine their effectiveness for Canada, as well as secure funding from governments for the information technology infrastructure needed to support a network of reporting systems with standardized data definitions management. Systems must be able to share data.<sup>306</sup>

A 2001 review of leading patient safety practices in Canada also highlighted the need to develop better reporting systems.<sup>307</sup> Health care organizations surveyed as part of the review indicated that adverse events are under reported at the local level because of the punitive culture in most organizations and a lack of resources for systematic data collection. A lack of appropriate tracking systems to identify adverse events and near misses was identified and current systems were felt to focus on adverse events rather than capturing the learning potential of near misses. The report recommended that new regional and national reporting systems be tested and evaluated at all levels of the system.

Factors going to the success of reporting systems in enhancing patient safety will depend upon the degree of engagement by health providers. Systems therefore need to be designed to provide incentives for reporting, ensure confidentiality while bolstering accountability, and emphasize a systems perspective over an individual perspective.<sup>308</sup>

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<sup>305</sup> For more information on this area, please refer to the Canadian "Other Legislative Instruments" section.

<sup>306</sup> National Steering Committee, *supra* note 21 at 15-19.

<sup>307</sup> G. Ross Baker & Peter Norton, *Patient Safety and Healthcare Error in the Canadian Healthcare System: A Systematic Review and Analysis of Leading Practices in Canada with Reference to Key Initiatives Elsewhere* (Ottawa: Health Canada, 2001), online: Government of Canada <[http://www.hc-sc.gc.ca/hcs-sss/pubs/care-soins/2001-patient-securit-rev-exam/index\\_e.html](http://www.hc-sc.gc.ca/hcs-sss/pubs/care-soins/2001-patient-securit-rev-exam/index_e.html)>.

<sup>308</sup> Barach, *supra* note 303.

## Other Legislative Instruments

This section includes two quality focused legislative initiatives that also overlap with and have significance for patient safety. First, we discuss legal frameworks that have some considerable history within Canadian health systems - rules of evidence that protect disclosures made in the course of quality assurance programs from use in other legal proceedings. Second, some provincial legislatures have used legislation to establish quality councils to provide advice about matters relating to quality in the health system and we briefly discuss the functions of these councils.

### Rules of Evidence and Privacy Legislation

All provinces and territories in Canada have extended legislative protection to quality assurance information. This legislation is designed to protect those who offer information in proceedings designed to maintain or improve quality control in health care settings by allowing evidence given in those contexts to be inadmissible in legal proceedings. In broad terms, all provinces and territories allow for information given to or prepared for quality assurance committees to be privileged. Quality assurance information does not include medical or hospital records concerning patients. Despite the broad similarities that exist, some variation exists across the country as to what counts as a legal proceeding from which the quality control committee information should be barred.

Evidence Acts and similar legislation are not the only legislation to consider. In recent years, federal and provincial/territorial governments have passed Privacy and Access to Information Acts. Quality of care committees often deal with identifiable patient information and may come to conclusions that have some bearing on matters important to patients or their representatives. The privileges granted under the rules of evidence may be at odds with privacy and access to information legislation and there is some variation across the country in this regard.

As mentioned, in most provinces, quality assurance privilege is granted in provincial Evidence Acts. For example, the Newfoundland *Evidence Act*<sup>309</sup> makes inadmissible any evidence given before the Provincial Perinatal Committee and the quality assurance and peer review committees of an organization or profession listed in the *Hospital and Nursing Home Association Act*.<sup>310</sup> Moreover, if a person is a witness in any legal proceeding, they cannot be asked and nor can they answer any question relating to information given to the review committees. The provision excludes original medical or hospital records from documents that can be privileged even if they were part of the

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<sup>309</sup> R.S.N.L. 1990, c. E-16, s. 8.

<sup>310</sup> R.S.N.L. 1990, c. H-8 renamed the *Health Care Association Act* per amendments in *An Act to Amend the Hospital and Nursing Home Association Act*, R.S.N.L. 1995, c. 36 and further am. by R.S.N.L.2001, c. 18.

documents reviewed by the quality assurance committee. Moreover, having been a member of or a witness to a quality assurance committee does not thereby render all the information the person has not compellable. Essentially, witnesses can be asked any questions so long as they are not in connection with the proceedings of the quality assurance committee.

The *Manitoba Evidence Act*,<sup>311</sup> by way of another example, provides that evidence given before a hospital committee is not compellable:

A witness in any legal proceeding, whether a party thereto or not, is excused from answering any question as to any proceedings before, or producing any report, statement, memorandum, recommendation, document, or information of, or made by, a committee to which this subsection applies and that is used in the course of, or arising out of, any study, research, or program carried on by a hospital or any such committee for the purpose of medical education or improvement in medical or hospital care or practice.<sup>312</sup>

Standards committees appointed under the *Hospitals Act*<sup>313</sup> and medical staff committees appointed to study or evaluate medical practice in a hospital are covered by this provision. Furthermore, those who provide evidence in committees are explicitly protected from liability:

Neither

(a) the disclosure of any information or of any document or anything therein, or the submission of any report, statement, memorandum, or recommendation, to any committee to which subsection 9(1) applies, for the purpose of its being used in the course of any study, research, or program carried on by a hospital or any such committee for the purpose of medical education or improvement in medical or hospital care or practice;

nor

(b) the disclosure of any information, or of any document or anything therein, that arises or of any such study, research, or program;

raises or creates any liability on the part of a person making the disclosure or submission.<sup>314</sup>

Further protection from disclosure is afforded by the *Manitoba Health Information Protection Act*.<sup>315</sup> Sections of this Act allow a trustee of personal health information to refuse to turn over information if the information was conveyed with the reasonable expectation of confidentiality or if the information was conveyed for quality assurance purposes. The provision reads:

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<sup>311</sup> C.C.S.M. c. E150.

<sup>312</sup> *Ibid.* at s. 9(1).

<sup>313</sup> *Supra* note 40.

<sup>314</sup> *Manitoba Evidence Act*, *supra* note 311 at s. 10.

<sup>315</sup> C.C.S.M. 1997, c. P33.5.

A trustee is not required to permit an individual to examine or copy his or her personal health information under this Part if:

...

- (c) disclosure of the information could reasonably be expected to identify a third party, other than another trustee, who supplied the information in confidence under circumstances in which confidentiality was reasonably expected;
- (d) the information was compiled and is used solely
  - (i) for the purpose of peer review by health professionals,
  - (ii) for the purpose of review by a standards committee established to study or evaluate health care practice in a health care facility or health services agency,
  - (iii) for the purpose of a body with statutory responsibility for the discipline of health professionals or for the quality or standards of professional services provided by health professionals, or
  - (iv) for the purpose of risk management assessment.<sup>316</sup>

Prior to 2004 Ontario was the only province that did not extend quality assurance privilege in their *Evidence Act*. This did not result in a lack of protection for this kind of information as privilege was granted on a case-by-case basis according to the common law test adopted by the Supreme Court in *Slavutych v. Baker*.<sup>317</sup> Specifically, for communications to be granted privilege under this test:

1. The communications must originate in a confidence that they will not be disclosed;
2. The element of confidentiality must be essential to the full and satisfactory maintenance of the relations between the parties;
3. Relation must be one in which the opinion of the community ought to be sedulously fostered; and,
4. The injury that would inure to the relation by the disclosure of the communications must be greater than the benefit thereby gained for the correct disposal of litigation.

In *Steep (Litigation Guardian of) v. Scott*<sup>318</sup> the Court accepted that the above conditions were met and refused to order the Kingston General Hospital to release quality assurance reports conducted by the hospital. In *Eliot v. Lo*,<sup>319</sup> however, the court found that none of the conditions were met and ordered that a skills and competency assessment of the defendant that was ordered by the College of Optometrists of Ontario be produced.

In 2004 the Ontario government passed the *Quality of Care Information Protection Act*<sup>320</sup> (*QCIPA*). This Act was welcomed by Ontario health care providers as it provided statutory protection for quality assurance information. *QCIPA* was passed along side the

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<sup>316</sup> *The Personal Health Information Act*, C.C.S.M. 1997, c. P33.5, s. 11(1).

<sup>317</sup> [1975] 1 S.C.R. 254.

<sup>318</sup> (2003), 62 O.R. (3d) 173.

<sup>319</sup> [2003] O.J. No. 1636.

<sup>320</sup> S.O. 2004, c. 3, Sch. B.

*Personal Health Information Protection Act (PHIPA)*<sup>321</sup> and prevails over that act insofar as any information disclosed to a quality of care committee cannot be released through the mechanisms of *PHIPA*.

Under *QCIPA*, quality of care information is defined as information that is prepared for a quality of care committee for the sole or primary purpose of allowing the committee to carry out its functions or as information that relates solely or primarily to any activity the a quality of care committee carries out. Quality of care information excludes, among other things, patient information collected for health care purposes and information that facilities are required by law to collect or maintain. A quality of care committee is defined as a body established by a health facility, a regulatory entity that carries on activities for the purposes of improving, maintaining the quality of care of a facility, a health care provider or a class of facilities or health care providers. The list of who qualifies as a quality of care committee has been extended by Regulations made under the Act to include homes for the aged, nursing homes, and laboratory or specimen collection centers.

The *QCIPA* provides very strong protection for those who provide information to quality assurance committees. Like other statutory protections offered in other provinces, persons who provide information to quality committees are not allowed to be asked about information provided to the committee in other proceedings, and evidence provided is inadmissible in other proceedings. This is fairly strong protection as it renders inaccessible to any future proceedings information that was given in the quality committees. In *QCIPA*, though, the protection for the person who gives the information is made much clearer:

No action or other proceeding may be instituted against a person who in good faith discloses information to a quality of care committee at the request of the committee or for the purposes of assisting the committee in carrying out its function.<sup>322</sup>

“Proceeding” is defined broadly enough to include court proceedings and proceedings under a professional college specified under the *Regulated Health Professions Act*.<sup>323</sup> This would appear that information given in a quality committee cannot be used against regulated healthcare providers. *QCIPA* does, however, explicitly exclude quality of care committees as proceedings and so it would appear that College quality committees would be permitted to institute actions against their members based on disclosures to, say, a facility-instituted quality committee. Given that the quality of care committees have a limited purpose, it is likely that disciplinary proceedings could not arise out of evidence given at a quality committee, though it is likely that competency issues could be brought out. This may be contrasted with the situation in the Northwest Territories. In their rules of evidence, a legal proceeding is defined in a manner that excludes conduct or competency hearings by a board struck under the authority of the *Medical Professions*

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<sup>321</sup> *Ibid.* at Sch. A.

<sup>322</sup> *Ibid.* at Sch. B, s. 8(1).

<sup>323</sup> S.O. 1991, c. 18.

*Act, the Midwifery Profession Act, the Dental Profession Act, or the Pharmacy Act* or a board or body connected with the professional organization to which the health care provider belongs.<sup>324</sup> So while the *Evidence Act* of the Northwest Territories extends privilege to quality of care information and does not allow matters relating to the committee to be compellable in a legal proceeding, it is clear that the information can be used for the purposes of conduct and competency inquiries by professional bodies.

In *QCIPA* there are statutory provisions allowing for disclosure of quality care information. Obviously, the committee is allowed to disclose information to the management of the body that struck the committee. Interestingly, however, the *Act* permits disclosure if the disclosure is necessary for protecting persons:

Despite subsection (1) [prohibiting disclosure of quality of care information] and the Personal Health Information Protection Act, 2004, a person may disclose quality of care information if the disclosure is necessary for the purposes of eliminating or reducing a significant risk of serious bodily harm to a person or group of persons.<sup>325</sup>

Presumably, one who sought to disclose quality of care information under this provision would have to meet a high burden of showing that disclosing the information truly was necessary for eliminating some serious threat. This provision appears to be unique to Ontario.

With respect to privacy legislation, as mentioned above, *QCIPA* is paramount to *PHIPA*. The Act explicitly holds that information that might otherwise be protected under *PHIPA* may be disclosed to a quality committee. Moreover, *QCIPA* does not permit quality of care information to be accessed under *PHIPA*.

While the protections offered by *QCIPA* are strong, they are not airtight. Arguably, however, the disclosures permitted are designed to enhance the safety of the health care system and attempt at striking a reasonable balance between ensuring the efficacy of quality committees, protecting the public from harm, and protecting persons who provide evidence before such committees.

British Columbia's privilege is contained in their *Evidence Act*.<sup>326</sup> Like all other acts, this legislation forbids witnesses being asked or answering questions regarding proceedings before quality committees and nor may documents used in quality assurance proceedings be produced. As well, like other legislation, those who disclose information or records to committees are protected from liability so long as they acted in good faith. Like other legislation, members of committees are not permitted to divulge the goings-on of committees except to a board of management or to an organization of health care professionals. For the most part, information and documents are not accessible under the

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<sup>324</sup> R.S.N.W.T. 1988, c. E-8.

<sup>325</sup> *Supra* note 320 at Sch. B, s. 4.4.

<sup>326</sup> R.S.B.C. 1996, c. 164.

British Columbia *Freedom of Information and Protection of Privacy Act*<sup>327</sup> (FOIPOP) and so the Evidence Act provisions take priority. However, there is a provision of FOIPOP that is paramount to the provisions of the *Evidence Act* insofar as the privacy commissioner has the power to require any public body to produce any document or examine any record despite the privilege that exist over the information or document. Public body is defined to include hospitals, mental health facilities, and regional boards of health.

### Strengths and Weaknesses

The patient safety movement argues that only open acknowledgement and discussions of unsafe episodes of treatment and care can result in learning from these incidents and implementing systems to prevent or minimize subsequent events. Evidence from within the health system and from other sectors suggests that all effective safety and quality programs depend upon the support of, engagement with, and involvement in safety and quality programs.<sup>328</sup> Without participation there is little hope that systems will improve the safety of treatment and care.

The rationale of quality assurance privilege is, therefore, that by eliminating the disclosure of certain information it would remove barriers that discourage health providers from participating freely in peer review and other quality and safety activities. These barriers include:

- fear of exposure within a medical culture that personalizes error and expects perfection.
- a tendency for the public, the media and the politicians to focus on blaming and punishing individuals.
- potential legal consequences for informational disclosure.
- concern that safety and quality data is not risk-adjusted and scientifically validated.
- skepticism about the motivation for and utility of safety and quality processes.

It has been demonstrated, in health and in other sectors, that when information is disclosed, participation in safety and quality programs decreases.<sup>329</sup> In other areas of law it is held to be reasonable to not disclose information where disclosure would be reasonably likely to impede collection of similar information in the future. It is argued therefore that effective evidentiary protections support the strong public interest in

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<sup>327</sup> R.S.B.C. 1996, c. 165.

<sup>328</sup> See *e.g.* discussions in Institute of Medicine, *To Err is Human: Building a Safer Health System* (Washington: National Academy Press, 2000) and in the Australian Safety and Quality Council, *The Public Interest in Healthcare Qualified Privilege Issues Paper* (Canberra: Australian Safety and Quality Council, 2001) [Australian Safety].

<sup>329</sup> Australian Safety, *ibid.* at 8.

ensuring that the health system provides treatment and care that is safe and is of good quality.

In all provinces and territories in Canada such protections exist for those who provide information to quality assurance committees. However, in *Building a Safer System*,<sup>330</sup> the National Steering Committee on Patient Safety recommended further reforms to the legal and regulatory frameworks that touch upon patient safety issues. Their recommendations included ensuring that quality assurance privileges extended under evidence acts and other legislation were sufficiently strong to ensure that those who provide information and participate in safety and quality assurance processes are protected from having their information used in future litigation. Absent sufficient protection, individuals who may have information that could assist facilities and professional bodies to maintain or improve the safety of health services may be reluctant to come forward for fear of finding themselves involved in litigation. The privilege ought to strike a balance between allowing individuals to speak freely in quality assurance committees and still allowing for relevant information to remain free of privilege and, thus, accessible to patients or their representatives. Moreover, whether the information gained by a committee can be used for competency and disciplinary purposes should also be clarified.

Conversely, the general weakness of such a system of privilege is that there is also a significant public interest in the disclosure of information. There are two primary interests in stake in respect of the free disclosure of information. The first could be characterized as the public interest in good government. There is a public interest in the management and operation of publicly funded activities being transparent and open to scrutiny by the public. The public should be aware of information about adverse events and of safety and quality improvement mechanisms. Openness encourages effective accountability for the use of public funds and the provision of public services. Second is the promotion of rights, both the right of individuals to know information pertinent to them and their privacy rights. As discussed above, it is clear that legislatures in Canada consider that the public interest in non-disclosure outweighs the individual interest, particularly as individuals have free access to documents, such as the medical record, that pre-existed involvement in, or were incidental to, the quality assurance process.

### **Health Quality Councils**

The first agency of its kind in Canada, Saskatchewan's Health Quality Council, was established in 2002 via statute. An independent agency, the Health Quality Council's legislative mandate includes monitoring and assessing the quality of Saskatchewan's health services, promoting quality improvement research, training and education and developing new clinical standards of care.<sup>331</sup> It examines a number of dimensions of

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<sup>330</sup> National Steering Committee, *supra* note 21.

<sup>331</sup> *The Health Quality Council Act*, S.S. 2002, c. H-0.04, s. 5.

quality, one of which is safety.<sup>332</sup> The Council advises government, health authorities and professionals on a number of health care quality and safety matters and is required to publish public reports on its activities.<sup>333</sup>

Alberta<sup>334</sup> has a similar body in place (the Health Quality Council of Alberta) with patient safety as an explicit part of its quality mandate. It is currently a Minister's initiative but in 2006 is to become through regulation a Regional Health Authority responsible for quality including safety) across the province.

In Quebec, the National Assembly adopted an Act instituting the office of the Commissionaire à la santé et au bien-être.<sup>335</sup> The Health and Welfare Commissioner will be responsible for assessing the results achieved by the health and social services system and providing the public with the necessary background for a general understanding of the actions undertaken by the Government to address the major issues in the health and social services arena. This agency does not appear to have a legislative mandate to address patient safety, but does have a mandate in respect of quality, which may be interpreted to include safety by the Commissioner.<sup>336</sup> As well, there is a Health Quality Council of Quebec (HQCQ). The HQCQ is a non-governmental, non-profit agency whose mission is to promote best practices in the improvement of health services quality in Québec.<sup>337</sup>

In 2005 Ontario announced it was establishing a Health Quality Council to monitor and report publicly on health system outcomes as part of its *Commitment to the Future of Medicare Act, 2004*,<sup>338</sup> although it is unclear to date whether this body will have a safety mandate.

### Strengths and Weaknesses

Most of these bodies are only relatively recently established or are not yet in place, accordingly it is too soon yet to assess either effectiveness or efficiency in any empirical sense in respect of patient safety. However, the mere fact that these bodies prioritize patient safety as a component of their mandate provides some leadership at the provincial level in respect of patient safety and quality, and must be presumed to have some positive effects, certainly in terms of prioritizing the issues and raising public awareness. It also provides a degree of transparency to the issues relating to patient safety and quality in health care by making information about the problems and the proposed solutions readily

<sup>332</sup> Saskatchewan, Health Quality Council, "Our Definition of Quality", online: HQC <<http://www.hqc.sk.ca/portal.jsp?UkPddzKMuGsuG554rvUx/+jxqNQVtQUGRrg1ubQfPiOedAKMVWLm2mDqxOUgPD9>>.

<sup>333</sup> *The Health Quality Council Act*, *supra* note 331 at s. 21.

<sup>334</sup> Alberta's Quality Council was established by Ministerial Order in February 2004.

<sup>335</sup> R.S.Q. C-32.1.1A.

<sup>336</sup> *Ibid* at s. 2.

<sup>337</sup> Health Council of Canada, "Who's Who in Health Quality?," online: HQC <<http://www.info-hcc-ccs.ca/20051117/story3.html>>.

<sup>338</sup> S.O. 2004, c.5.

available to the public. Lastly, some of these bodies are specifically designed to monitor government processes in improving quality and patient safety or in implementing reforms that include patient safety related initiatives. This can only, one hopes, improve accountability.