health law in Canada
Canadian federalism and the regulation of health care

Canada, like the United States, is a federal state with a constitution that divides legal authority between the federal government and, in Canada's case, the provinces. In some areas of the law, however, the Canadian Constitution provides no exhaustive or explicit grant of authority, and health care is one of those amorphous areas. The Constitution allocates direct power over hospitals to the provinces and the remaining authority to regulate health care is derived from more general Constitutional powers that are divided between the federal and provincial governments. The result is that provision of health care in Canada is funded, delivered and regulated under a complex mosaic of rules and rule-makers, and the rules are constantly evolving.

Broadly speaking, the federal government is primarily responsible for the regulation of drugs and medical devices, while the provinces and territories are primarily responsible for the delivery of health care and health insurance, and for the regulation of health professionals. The federal government also exerts significant control over provincial health insurance programs through its spending power. Due to the potential conflicts that result from this power sharing, all levels of government rely on the court system to clarify jurisdictional issues.

Despite the complexity of the legal framework, and the focus on containing costs that comes with public funding, estimated spending on health care in Canada exceeded $183 billion in 2009. Of this amount, an estimated $129 billion was from public sources and $54 billion was privately funded.1

federal authority and legislation

The key Constitutional powers related to the federal government's authority over health care are those relating to taxation, spending, public property and the criminal law, as well as the general power "to make Laws for the Peace, Order, and Good Government of Canada".2

a) funding – the Canada Health Act

The broad Constitutional powers possessed by the federal government allowed it to begin funding a national single-payer health care system in 1966, and to update the system in 1984 with passage of the Canada Health Act. The Canada Health Act is a cornerstone of what Canadians call the "Medicare" system but it does not directly regulate the delivery of health care. Instead,

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2 Constitution Act: 1867.
the Canada Health Act establishes conditions that provincial health insurance programs must meet in order to receive federal funding. No province can afford to forego federal funding, and the Canada Health Act thus ensures that each provincial health insurance system is:

- publicly administered (operated by a public authority on a non-profit basis),
- comprehensive (covers all insured health services),
- universal (provides the insured services to 100% of insured persons),
- portable (imposes no minimum period of residence in a province and permits temporary absences), and
- accessible (offers uniform terms and conditions that do not impede access).

b) regulatory legislation

The federal government also uses its Constitutional authority over the criminal law as a means by which to regulate the sale of drugs, medical devices and related products. Key statutes are the federal Food and Drugs Act, the Controlled Drugs and Substances Act and the Criminal Code. Federal regulatory statutes are structured formally as criminal law in that they establish prohibitions and penalties, including imprisonment, but in practice they operate as typical regulatory statutes intended to protect public health.

Drug and Medical Device Approval Processes

The Food and Drugs Act governs which drugs can be manufactured, marketed and sold in Canada. Medical devices, medical gases, blood products, cosmetics, and "natural" health products such as vitamins and minerals are also regulated under the Food and Drugs Act.

A “drug” is defined broadly to include:

… any substance or mixture of substances manufactured, sold or represented for use in

a. the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,

b. restoring, correcting or modifying organic functions in human beings or animals, or
c. disinfection in premises in which food is manufactured, prepared or kept.3

The Food and Drugs Act establishes approval processes and sets standards for the manufacture, testing, packaging and labelling of regulated products. Applications for approval to market drugs and related products in Canada are reviewed by the Health Products and Food Branch (HPFB) of Health Canada.4

In the case of new drugs, the HPFB will review pre-clinical test results before authorizing clinical trials in Canada. If acceptable clinical trial results indicate that the drug has potential therapeutic value that exceeds its risks, the applicant may file a New Drug Submission (NDS). An NDS typically consists of 100-800 binders of data and other material on the safety, efficacy and quality of the product, as well as the information that the manufacturer intends to provide to health care providers and users. Applications for generic drugs involve a much shorter process to demonstrate that the generic product is as safe and effective as the brand-name product.

3 Food and Drugs Act, R.S., 1985, c. F-27, s. 2.
4 Exceptions can be made for limited use of therapeutic products that have not yet been authorized for sale in Canada. The Special Access Program (SAP) allows health care practitioners to request limited access to unauthorized products for emergency use or if conventional therapies have failed, are unsuitable or are unavailable to treat a patient. The SAP can also respond to specific health crises, such as an outbreak of a communicable disease.
Medical devices are classified into four categories according to the level of risk associated with their use, and the level of regulatory review escalates with the level of risk. Class I devices present the least risk and require no medical device licence but products in the three higher-risk categories do require licences before being sold in Canada. Similarly, natural health products must be reviewed and licensed before being sold.

The HPFB has established targets for the time it takes to complete its reviews. The target is 300 days for new drugs, and 180 days for generic drugs. The target for medical devices is 75 days or less, depending on risk category. Targets for natural health products are being developed. Applicants can obtain an expedited “priority review” for new drugs or Class III and IV medical devices if: (i) the product is intended for the treatment, prevention or diagnosis of very serious illnesses or conditions; and (ii) no equivalent product is marketed in Canada.

If the product is approved for sale in Canada, the HPFB will issue licenses for medical devices and natural health products and, for drugs, it will issue a Notice of Compliance (NOC). The federal Patent Act provides for linkages between the drug approval process and the registration of patents in Canada. Patent Act provides for linkages between the drug approval process and the registration of patents in Canada. Patents last for 20 years.

Post-Approval Regulation

Approval of the product does not end the regulatory process at the federal level. The Food and Drugs Act also requires that all establishments engaged in the fabrication, packaging, labelling, importation, distribution or wholesale of drugs and natural health products must obtain an “establishment licence” that demonstrates compliance with “Good Manufacturing Practices” (GMP) as determined by Health Canada. Importers must prove that imported products are produced in facilities that meet these same GMP requirements. Canada has agreed to recognize GMP standards and licenses granted to facilities in Australia, the European Union and some additional countries in Europe, but has no similar agreement with the United States. Establishments that manufacture, import or sell medical devices must also meet certain regulatory requirements. Licensed establishments are also subject to ongoing monitoring and inspection by Health Canada.

In addition, the prices of patented drugs are regulated at the federal level by the Patented Medicine Prices Review Board, which has a mandate to ensure that prices are not “excessive”. Moreover, drugs and medical devices must be approved at the provincial level in order to be covered under provincial health insurance systems. This process is facilitated by the work of the Canadian Agency for Drugs and Technologies in Health (CADTH), an independent non-profit agency with a mandate “to provide credible, impartial advice and evidence-based information about the effectiveness of drugs and other health technologies to Canadian health care decision makers.” The CADTH focuses strongly on cost-effectiveness and issues reports through its “Health Technology Assessment” and “Optimal Medication” programs. It also implements a “Common Drug Review” process to provide formulary recommendations for all provinces except Québec. Nonetheless, the provinces also retain individual requirements.

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5 See Patented Medicines (Notice of Compliance) Regulations, SOR/93-133.


c) antitrust legislation

Investors who seek to enter the Canadian health care market by way of mergers and acquisitions must comply with Canada’s federal *Competition Act*. The parties must notify the Competition Bureau if: the value of the target company’s Canadian assets or revenues exceed $70 million and the combined Canadian assets or revenues of the parties and their affiliates exceeds $400 million. The Bureau can block a transaction if it determines that the transaction is likely to “substantially” prevent or lessen competition in the marketplace.

The *Competition Act* also includes rules against cartel behavior and “abuse of dominance”, price maintenance, exclusive dealing, tied selling and refusal to deal. In addition, private parties can in some cases initiate legal action under the *Competition Act* or request that the Competition Tribunal review another party’s commercial practices. The Competition Bureau also enforces the *Consumer Packaging and Labelling Act*.

provincial authority and legislation

The Canadian Constitution grants specific powers over hospitals to the provinces, as well as broad powers to make laws regulating “property and civil rights” and “generally all matters of a merely local or private nature” in the province. As a result, provincial governments are responsible for the regulation of health care delivery and health insurance, although the federal government’s provision of funding through the *Canada Health Act* ensures that provincial health insurance programs meet certain criteria. More than 90% of hospital and physician care is funded publicly but government funds less than half of all prescription drug expenditures and spends relatively little on dental and eye care.⁹

Policy makers and researchers at the provincial level frequently express concerns about the fiscal sustainability of the health care system, and the provinces are under pressure to reduce costs. The Ontario government has the largest budget and is thus an important driver of policy reform. For example, in May 2010, the Ontario legislature passed a measure to prohibit generic drug manufacturers from paying pharmacists a “professional allowance” to supplement the amount paid by the province when a covered prescription is filled.¹⁰ Another measure will require hospitals to create “quality improvement plans” and to link compensation for top hospital executives to the achievement of quality goals.¹¹

Private insurance can be obtained to cover “enhanced” care or services that are not covered under provincial plans, and health care “tourists” can pay cash for care but provincial statutes prohibit the use of private insurance to pay for services that are already covered under provincial insurance schemes.¹² However, in 2005 the Supreme Court of Canada cast doubt on the constitutionality of such prohibitions with its *Chaoulli* decision.¹³ A divided court held that Québec’s prohibition against private insurance violated the rights of patients who otherwise were required to wait long periods to receive publicly-funded care. A minority of the Court would have applied the same ruling to the country as a whole. For now, the decision applies only in Québec but it may yet have important national effect.

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hospital care

Canadian hospitals spent an estimated $50 billion on service delivery in 2009, of which approximately 40% was spent in Ontario.14

public hospitals and clinics

Hospitals in Ontario are, with few exceptions, private not-for-profit corporations and most receive the vast majority of their funding from public sources and are therefore referred to as “public” hospitals.

Each province has a Public Hospitals Act to govern the establishment, management and funding of publicly-funded hospitals. Funding is generally allocated through a global budget as opposed to a fee-for-service basis but activity-based funding has also been implemented on a limited basis.15 Provinces may also use their funding to influence procurement practices at public hospitals by requiring competitive bidding and encouraging group purchases.16

Smaller clinics may be licensed to provide insured surgical, diagnostic or therapeutic services outside a hospital setting. In Ontario, these facilities are regulated under the Independent Health Facilities Act and are reimbursed by the province on a fee-for-service basis. The great majority of these facilities offer diagnostic services such as x-rays and ultrasounds. Payments to independent health facilities in Ontario exceeded $270 million in 2003-2004.17

private hospitals and clinics

Truly “private” hospitals are very rare in Canada, primarily due to the statutory prohibition against private insurance for services that are already publicly-funded.18 The Canada Health Act also prohibits co-payments or “extra billing” for covered services.19 However, nothing in the Canada Health Act or provincial statutes prohibits the operation of fully private hospitals or clinics for patients that can afford to pay the full cost of services without insurance.

A number of clinics across Canada do in fact operate outside the public system to provide a wide variety of services, including MRIs and other diagnostic testing, cataract surgery, hip and knee replacements.20 In addition, clinics are free to provide services like elective cosmetic surgery that are not covered under provincial insurance plans.

pharmaceutical products

Total spending on drugs in Canada was forecast to reach $30 billion in 2009, of which more than 80% was for prescription drugs. Spending grew more than 9% annually between 1985 and

16 For example, see Ontario’s “Supply Chain Guideline” applicable to health facilities that receive more than $10 million annually in provincial funding, online: Ontario Ministry of Finance, http://www.fin.gov.on.ca/en/ontariobuys/documents/scg.pdf
17 Office of the Auditor General of Ontario, 2006 Annual Report, s. 4.8, pp. 301-302, Fig. 1, online: http://www.auditor.on.ca/en/reports_en/en06/408en06.pdf
19 Canada Health Act, R.S., 1985, c. C-6, ss. 18-20.
2007, significantly faster than the rate for health care expenditures overall but growth has slowed significantly in recent years. Public funding accounts for only about 45% of total prescription drug expenditures.21 The federal government is responsible for approving drugs for sale in Canada, and the provinces determine whether a drug is added to a formulary to be covered under the provincial drug benefit plan.

Both the federal and provincial governments play a role in regulating drug prices.22

c) physicians and other health professionals

Expenditures for physician services were forecast to exceed $25 billion in 2009, with the public sector funding 98% of that amount. Spending on other health professionals is primarily for dental and vision care, physiotherapy and private nurse care – this spending exceeded $17 billion in 2007, of which more than 92% was privately funded. Roughly half of this private expenditure was funded out-of-pocket, while the other half was covered under private insurance plans.23

Nearly all physicians and health professionals operate privately, rather than as government employees and generally bill on a fee-for-service basis, even when operating within hospitals. Specialized legislation in each province governs the health professions in terms of licensing requirements and scope of practice, including rights to prescribe drugs and authorize tests. Ontario recently expanded the scope of practice for a number of health professionals, in particular by allowing them for the first time to prescribe certain types of drugs. Pharmacists were granted this power and also the authority to dispense drugs remotely through the use of audiovisual links to under-served locations.

d) long-term care

Spending on long-term care facilities in Canada rose to an estimated $16 billion in 2009, approximately 70% of which was provided by the public sector.24 Long-term care facilities are licensed provincially and many are privately owned and operated but municipalities also operate many facilities. In Ontario, these facilities are regulated under the Long-Term Care Homes Act and may provide social services as well as medical, nursing and related services.25

other business law topics

a) private health insurance

Approximately 75% of Canadian residents are covered under some form of private health insurance, either as a supplement to public insurance, particularly for prescription drug coverage, or because they are ineligible for public plans. Premiums paid exceeded $26 billion in 2008. Many individuals also purchase disability insurance, which is generally not covered under public plans.26

b) marketing and advertising regulations

A variety of federal and provincial statutes regulate the ways in which health care products and services can be marketed, including the federal Competition Act as well as provincial consumer

22 See footnote 7 for the federal role. For provincial rules see, for example, the Ontario Drug Benefit Act, R.S.O. 1990, c. O.10.
protection and health-related statutes. The federal *Food and Drugs Act* establishes a general rule for the advertising of drugs:

> no person shall label, package, treat, process, sell or advertise any drug in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety.

More specific rules under this statute apply to advertisements of any drug as a treatment for certain listed diseases or conditions, or as a contraceptive.

In addition, the Pharmaceutical Advertising Advisory Board (PAAB) is an independent, multidisciplinary body that provides review and clearance of drug marketing materials. It also administers the PAAB Code of Advertising Acceptance, which applies to advertising of prescription and non-prescription pharmaceutical products, biologicals and natural health products directed at licensed members of most health professions. Compliance with the PAAB Code is voluntary but compliance is strongly encouraged by Health Canada and required by some industry associations.

Various other industry associations have undertaken a host of other self-regulation initiatives. For example, Canada's Research-Based Pharmaceutical Companies (Rx&D) has issued a Code of Marketing Practices for its members, Canada's Medical Technology Companies (MEDEC) has published a Code of Conduct for its members, and the Canadian Association of Medical Publishers (CAMP) has issued guidelines for all advertising appearing in publications directed to health professionals. More generally, an organization named Advertising Standards Canada administers the influential Canadian Code of Advertising Standards.

c) privacy legislation

Key privacy legislation includes the federal *Personal Information Protection and Electronic Documents Act* (PIPEDA) governing the collection, use and disclosure of personal information (other than employee information), including cross-border disclosures. Provincial laws in British Columbia, Alberta and Québec establish similar controls over personal information, including employee information and health information. In Ontario, the *Personal Health Information Protection Act* applies to any person or entity that receives “personal health information” from “health information custodians” such as hospitals or regulated health professionals.

Canadian privacy legislation is based on the same 10 privacy principles adopted worldwide:

1. Accountability
2. Identifying Purposes
3. Consent
4. Limiting Collection
5. Limiting Use, Disclosure and Retention
6. Accuracy
7. Safeguards
8. Openness
9. Access
10. Challenging Compliance
d) litigation

Personal injury claims and litigation generally are less common in Canada than in the United States for several reasons, including the Supreme Court of Canada’s cap on damages that may be awarded for pain and suffering, which stands at approximately $320,000 per person for the worst injuries. Punitive damages are also modest if awarded, which is rare. Other factors include the general rule that the loser of a court case pays a substantial portion of the victor’s legal costs, and the fact that cases are tried before a judge and not a jury.

However, class actions suits are becoming more common in Canada, for some of the same reasons that individual tort claims are relatively less common. In addition, the Supreme Court of Canada has held that the Canadian Charter of Rights and Freedoms applies not just to government actions but also to private entities like hospitals that “act in furtherance of a specific governmental program or policy”.27

e) labour / employment

In legal terms, employment in Canada is on a modified “employment at will” concept, with severance entitlements established both by statute and at common law.

a cautionary note.

The foregoing provides a summary of aspects of Canadian law that may interest persons considering doing health business in Canada. McMillan LLP lawyers prepared this information, which is accurate at the time of writing. Readers are cautioned against making decisions based on this material alone. Rather, any proposal to do health business in Canada should be discussed with qualified professional advisers.

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